IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION
MDL No 2804
THIS DOCUMENT APPLIES TO ALL No 17-MD-2804
CASES Hon Dan A Polster
_____/

HIGHLY CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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FRIDAY, FEBRUARY 1, 2019
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Videotaped Deposition of STACEY BECKHARDT, held at the Law Offices of Skikos Crawford Skikos & Joseph, One Sansome Street, Suite 2830, San Francisco, California, beginning at 9:40 a m , before Sandra Bunch VanderPol, FAPR, RMR, CRR, CALIFORNIA CSR #3032

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(Appearances continued on next page)

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RYAN WONG, Videographer
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I N D E X

Examination by: Page
MR. CARTMELL 10
MR. CRAWFORD 332
MR. GASTEL 372

--o0o--

E X H I B I T S

Teva-Beckhardt Exhibits Page
Exhibit 1 Actiq and Fentora pictures - promotional 21
Exhibit 2 FDA Approved Indication of Actiq and Fentora 51
Exhibit 3 Email chain dated 11/25/03 re "Actiq Investigation segment on Channel 6 News," Bates TEVA_MDL_A_03316708 - 710 71
Exhibit 4 Email chain dated 11/21/01 re "Non-flattering segment on Channel 6 News, Bates TEVA_MDL_A_03316701 - 702 83
Exhibit 5 PoliceOne.com article, "Increase In Abuse Reported of Narcotic Lollipos for Cancer Patients, dated 4/27/04 85
Exhibit 6 Email chain dated 1/24/05 re "JAMA (1/19): Research Letter Finds Increased Reports of Methadone Diversion and Abuse," Bates TEVA_MDL_A_03272549 - 551 96
Exhibit 7 Actiq Risk Management Program, dated 8/1/01, Bates TEVA_MDL_A_03272088 - 117 114
Exhibit 8 Cephalon letter dated 9/19/06 to FDA re "Amendment to NDA: Response to FDA Correspondence Regarding RiskMAP," Bates TEVA_MDL_A_00028341 - 691 144

EXHIBITS

Teva-Beckhardt Exhibits	Page
Exhibit 9 Memorandum dated 4/26/08 to ALSDAC from Rappaport re "Overview of the May 6, 2008 ALSDAC Meeting," Bates TEVA_MDL_A_07864371 - 502	161
Exhibit 10 PowerPoint Slides titled, "Fentora Strategic Marketing Plan, 2007, Bates TEVA_MDL_A_07846839 (Native format)	170
Exhibit 11 Article in "The Street," titled, "Cephalon Eyes New Fentora Use, no Bates	183
Exhibit 12 ACTIQ 2002 Marketing Plan, Bates TEVA_MDL_A_00454816 - 959	195
Exhibit 13 Document titled, "Risk Management Program vs Actiq Marketing Plans," Bates TEVA_MDL_A_03272088 and 2882	228
Exhibit 14 Document titled, "Risk Management Program vs Actiq Marketing Plans," Bates TEVA_MDL_A_03272088 and 816	229
Exhibit 15 Document titled, "Risk Management Program vs Actiq Marketing Plans," Bates TEVA_MDL_A__03272088 and 816	237
Exhibit 16 2013 Actiq Marketing Plan, Bates TEVA_CHI_00042882 - 950	238
Exhibit 17 Document titled, "Risk Management Program vs Actiq Marketing Plans," Bates TEVA_MDL_A_03272088 and 882	252
Exhibit 18 US DOJ document dated 9/29/08, "Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing," no Bates	262

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///

EXHIBITS

Teva-Beckhardt Exhibits	Page
Exhibit 19 Cephalon document, "Cephalon Announces Positive Results for Fentora (fentanyl buccal tablet) for Breakthrough Pain in Patients with Chronic Low Back Pain," Bates TEVA_MDL_A_07366254 - 256	277
Exhibit 20 PowerPoint slides, "FAST Team Meeting, dated 1/18/07, Bates TEVA_CHI_00006142 (Native format)	288
Exhibit 21 Email dated 7/27/07 re "FAST Team meeting," attaching PowerPoint slide titled, "FAST Team Meeting," dated 7/20/07, Bates TEVA_MDL_A_00010346, TEVA_MDL_A_0010347_001 through _082	299
Exhibit 22 Email chain dated 2/4/06 re "Pain Franchise 2006 Budget Revised Draft 2 3 06 doc, with attachment, Bates TEVA_MDL_A_02375504 - 509	333
Exhibit 23 Email chain dated 4/9/04 re "Important News: New Tools Available," Bates TEVA_MDL_A_09667462 - 463	345
Exhibit 24 Email dated 12/13/06 re "Do You Still Have Pain," with attachment, Bates TEVA_MDL_A_01399742 - 750	345
Exhibit 25 Educational Grant Draft Request; Payee, American Pain Foundation; Amount, $75,500, Bates TEVA_MDL_A_01174115 - 147	345
Exhibit 26 Education Grant Request; Payee, American Chronic Pain Association; Amount, $33,800, Bates TEVA_MDL_A_01089593 - 596	361
Exhibit 27 Email dated 10/2/06 re "ACPA brochure, etc ," with attachment, Bates TEVA_MDL_A_02935839 - 841	361

EXHIBITS

Teva-Beckhardt Exhibits	Page
Exhibit 28 American Chronic Pain Association pamphlet, "Managing Breakthrough Pain (BTP), no Bates	361
Exhibit 29 Educational Grant Draft Request; Payee, American Pain Foundation; Amount, $25,000, Bates TEVA_MDL_A_01089587 - 589	366
Exhibit 30 Email chain dated 6/19/07 re "APF Distributed the Treatment Options Guidebook to Soldiers and Family Members," with attachment, Bates TEVA_MDL_A_01090493 - 579	367
Exhibit 31 Email dated 3/21/05 re "TIME (3/28) Reports on OxyContin Abuse and Diversion in Appalachian Virginia," Bates TEVA_MDL_A_03274246 - 247	378
Exhibit 32 Email dated 11/17/06 re "Pain Franchise News Weekly Monitoring Report 11-17-06," with attachment, Bates TEVA_MDL_A_07848758 - 773	385
Exhibit 33 Email dated 2/16/07 re "Pain Franchise News Weekly Monitoring Report 2-16-07," with attachment, Bates TEVA_MDL_A_02049666 - 675	394
Exhibit 34 Email dated 8/11/07 re "Pain Franchise News Weekly Monitoring Report 8-10-07," with attachment, Bates TEVA_MDL_A_01864226 - 251	401
Exhibit 35 Email dated 5/30/08 re "Pain Franchise News Weekly Monitoring Report 5-30-08," with attachment, Bates TEVA_MDL_A_02048242 - 251	405
Exhibit 36 PowerPoint slides titled, "Welcome to AD Hydrocodone Launch Preparation Kickoff, dated 4/16/13, not Bates (Native format)	410

BE IT REMEMBERED that on Friday, the 1st day of February commencing at the hour of 9:40 in the law offices of Skikos Crawford Skikos & Joseph, One Sansome Street, Suite 2830, San Francisco, before me, Sandra Bunch VanderPol, a Certified Shorthand Reporter in and for the State of California, personally appeared.

STACEY BECKHARDT,

called as a witness (Cephalon/Teva), who, having been duly sworn, was thereupon examined and interrogated as hereinafter set forth.

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THE VIDEOGRAPHER: We are now on the record. My name is Ryan Wong. I'm a videographer for Golkow Litigation Services. Today's date is February 1st, 2019, and the time is 9:40 a.m.

This video deposition is being held in San Francisco, California, in the matter of National Prescription Opiate Litigation, for the United States District Court, Northern District of Ohio.

The deponent is Stacey Beckhardt.

Will counsel please identify themselves for the record.

MR. CARTMELL: Tom Cartmell, on behalf of the plaintiffs.

MR. CRAWFORD: Mark Crawford, on behalf of the plaintiffs.
MR. WOLFE: Evan Wolfe, technology support for plaintiffs.
MR. JENSEN: Dylan Jensen, for the plaintiffs.
MS. GOODSPEED: Taylor Goodspeed, Jones Day, on behalf of Walmart.
MR. GASTEL: Ben Gastel, from Branstetter, Stranch & Jennings, on behalf of the Tennessee plaintiffs.
MR. JOHNSON: Joel Johnson, of Williams & Connolly, on behalf of Cardinal Health.
MS. BARBER: Maureen Barber, with Morgan Lewis, on behalf of the Teva defendants.
MR. JAMES: Collie James, Morgan Lewis, on behalf of the witness and the Teva defendants.
THE VIDEOGRAPHER: On the phone?
MS. BALASTER: I'm Mary Balaster, of Reed Smith, on behalf of AmerisourceBergen Drug Corporation.
MS. RIGBERG: Karen Rigberg, on behalf of Arnold & Porter, for the Endo and Par defendants.
MR. CARTMELL: Anyone else?
(No response.)

THE VIDEOGRAPHER: The court reporter is Sandy VanderPol and will now swear in the witness.
THE REPORTER: Raise your right hand, please.
Do you solemnly swear or affirm that the testimony you are about to give in this proceeding will be the truth, the whole truth, and nothing but the truth, so help you God?
THE WITNESS: I do.

EXAMINATION

BY MR. CARTMELL:
Q. Good morning.
A. Good morning.
Q. Will you please state your full name for the record.
A. It's Stacey Beckhardt.
Q. Ms. Beckhardt, my name is Tom Cartmell. I'm going to be asking you questions today. I represent various plaintiffs in this lawsuit that has been filed against various drug manufacturers in an MDL proceeding that's pending in Ohio. Do you understand that?
A. Yes, I do.
Q. Have you ever been deposed before today?

A. No.
Q. Let me say a few things real quick just so we can have this go as efficiently as possible.
I'm going to ask you questions, and if at any time you don't understand one of my questions, I'm going to ask that you go ahead and tell me that, and then I will try to restate it or rephrase it so that you can understand it; is that okay?
A. Yes.
Q. The other thing is I want you to be comfortable at all times today during the deposition. So if at any time you need to take a break for any reason, if you need to go to the restroom or talk to your counsel or anything, just let me know that, and we will be fine with taking a break; okay?
A. Okay.
Q. Now, you understand that you're under oath today?
A. Yes, I do.
Q. Okay. And where are you currently employed?
A. BioMarin.
Q. BioMarin?
A. Huh-huh.

Q. What is BioMarin?
A. It's a pharmaceutical company.
Q. Where is BioMarin located?
A. It's located in San Rafael, California.
Q. Is that just outside San Francisco?
A. Yes, it is.
Q. How far from San Francisco?
A. Probably about 15 miles, give or take. Marin County.
Q. And where -- I'm sorry.
What is your current position at BioMarin?
A. I am Senior Director for the Global Patient Advocacy Network.
Q. Is that a public relations type position?
A. No. It's an internally facing position that coordinates patient advocacy.
Q. Is it true that you were previously employed by a pharmaceutical company called Cephalon?
A. Yes, I was.
Q. And is it true that you were also employed previously at a pharmaceutical company called Teva Pharmaceuticals?
A. Yes.

Q. I'm going to be asking you questions about your time at Cephalon Pharmaceutical primarily, but may ask you questions today about your time at Teva Pharmaceuticals as well; okay? Do you understand that?
A. Yes.
Q. Now, my understanding is that you were employed at Cephalon and Teva from the time period 2001 through approximately -- was it April of 2012?
A. Yes.
Q. Okay. And I think during that period of time you worked for Cephalon until Teva Pharmaceuticals actually acquired Cephalon sometime in 2011; is that correct?
A. That's correct.
Q. And then after Teva Pharmaceuticals acquired Cephalon, you continued on at Teva for a period of approximately six months; is that right?
A. That's correct.
Q. Why was it that you left Teva after six months, after Teva acquired Cephalon?
A. They had no position available for me full-time.
Q. Were you terminated?

A. Yes.
Q. Were you given any reasons for your termination specifically?
A. It was a head count issue.
Q. Did they do away with your position?
A. Yes.
Q. And as a result of your termination from Teva, did you have a severance agreement?
A. Yes, I did.
Q. And in that severance agreement, were you offered and did you accept some type of severance payment from Teva?
A. Yes, I did.
Q. How much was that payment that Teva made to you?
A. It was one year's worth of salary.
Q. Which at that time would have been how much?
A. I don't recall exactly.
Q. Can you ballpark it for me?
A. Probably about 125,000.
Q. You were only making 125,000 in 2012?
A. Give or take.
Q. Okay. Did the agreement that you had with Teva Pharmaceuticals upon your termination

include any type of statement that you were not to disparage Teva or Cephalon in any way?
A. No.
Q. Do you still have a copy of that agreement?
A. Not to my knowledge.
Q. Are you here today represented by counsel?
A. Yes, I am.
Q. Who is representing you?
A. Collie James and --
Q. And --
A. -- Maureen Barber.
Q. I'm sorry. I cut you off. Go ahead and tell me who they are again.
A. Collie James and Maureen Barber.
Q. Mr. James or Ms. Barber, are they Teva's lawyers?
A. Yes, they are.
Q. And I take it you had a chance to meet with them prior to your deposition today?
A. Yes.
Q. When was it that you first met with Teva's lawyers in preparation for your deposition today?

A. Yesterday.
Q. And had you talked to them, though, over the phone about the deposition prior to that?
A. I had a phone call that explained the circumstance, and that I was going to be deposed.
Q. When was that phone call?
A. Probably -- I don't know exactly. Maybe a month ago or so.
Q. And that phone call that you referenced approximately a month ago, how long did that take?
A. About 30 minutes.
Q. And then -- excuse me. Strike that.
And then your meeting with Teva's lawyers yesterday, where was that meeting?
A. It was at their San Francisco offices.
Q. What's the name of the law firm; do you know?
A. Morgan Lewis.
Q. So you went to Morgan Lewis's law firm and had a meeting yesterday. Approximately what time did you arrive?
A. 8:30 in the morning.
Q. And how long was your meeting with

Teva's lawyers yesterday?
A. Until 4:45.
Q. During that meeting with Teva's lawyers, did you get a chance to prepare for today's deposition?
A. I was given an understanding of what the deposition was going to be like.
Q. Did you review any documents at that time?
A. Yes.
Q. Have you maintained those documents?
A. No.
Q. So is it fair to say that your only preparation for today's deposition has been about a 30-minute phone call a month ago and then a meeting with Teva's lawyers yesterday from approximately 8:30 until 4:30?
A. That's correct.
Q. Have you had any discussions with anybody else, whether or not they are lawyers from Morgan Lewis, about today's deposition and in order to prepare for today's deposition?
A. There are some people who know I am here. But nobody has prepared me.
Q. Who is it that knows you're here?

A. Several of my colleagues at work, because I had to get the time off.
Q. Did you ever talk to any of your former colleagues at Cephalon or Teva about today's deposition?
A. One person who is a current leader within my company.
Q. Who is that?
A. Chuck Buckler. He was the head of oncology sales.
Q. You said he was the head of oncology sales. Are you referring to the time period when you were at Cephalon?
A. Correct.
Q. Was Mr. Buckler involved at all in the marketing or promotion of the opioid products at Cephalon?
A. Yes.
Q. In what capacity?
A. Marketing to the oncology community.
Q. And approximately what period of time were you contemporaries together?
A. Probably maybe -- I don't know for sure.
Q. Now, Ms. Beckhardt, you worked at

Cephalon from 2001 until 2011. And is it fair to say that during the majority of that time, you were working in the Public Relations Department at Cephalon?
A. For about eight of those years.
Q. Would that have been from approximately November of 2001, for eight years after that?
A. Yes.
Q. Until sometime in 2009 or '10; is that right?
A. Something like that.
Q. And at that time, in late 2009 or 2010, did you change positions?
A. Yes, I did.
Q. What was your new position at that time?
A. It was focused on -- solely on patient advocacy across all of our therapeutic areas, both in development and marketed.
Q. During your time in public relations from 2001 to late 2009 or 2010, were you working as a part of your duties with the pain franchise at Cephalon?
A. Yes, I was.

Q. And when I refer to pain -- the pain franchise, I'm referring to the franchise that included drugs that were being promoted and sold by Cephalon, namely the opioid narcotics called Actiq and Fentora. Do you understand that?
A. Yes, I do.
Q. The pain franchise that you were involved with from 2001 through the end of 2009, were there any drugs in that franchise other than the opioid narcotics named Actiq and Fentora?
A. There was a product called Amrix, but it's not an opioid medication.
Q. Is Amrix a narcotic?
A. No. It is a muscle relaxant.
Q. Is it more like an NSAID, like --
A. Yes.
Q. -- Advil, Tylenol, or something like that?
A. It is prescription strength, but it is more in that class of medicine.
Q. I see. So during the time that you were in public relations with Cephalon and working with the pain franchise, the only two opioid narcotic drugs that you were overseeing were a drug called Actiq and a drug called Fentora; is that fair?

A. That's correct.
(Exhibit No. 1 was marked.)
MR. JAMES: Two copies?
MR. CARTMELL: Yes. Okay. I'm not sure we have three to give out.
Q. Ms. Beckhardt, I've handed you a copy of a document that has photographs or pictures of two medications, I believe, that Cephalon was promoting, marketing, and selling during the time period that you were there; do you see that?
A. Yes, I do.
Q. Okay. And I want to talk a little bit about these medications. The jury has by now seen pictures of these opioid narcotics we're talking about. But if you could, why don't you explain to the jury what this represents as far as the opioid narcotic medications?
MR. JAMES: Objection. Vague and ambiguous.
MR. CARTMELL: Strike that. I will start over. That's a good objection.
Q. Now, Exhibit 1 includes on the left, Ms. Beckhardt, a picture of -- it looks like to be a woman who is putting in her mouth what looks to be something like a lollipop. Tell us what that is.
A. It's an Actiq unit.

Q. When you say "an Actiq unit," Actiq, the drug, is a fentanyl-based opioid narcotic; is that correct?
A. Yes, it is.
Q. And this unit, when you say "unit," does that mean one of these lollipop-type of medications? Is that a unit?
A. Yes, it is.
Q. Okay. And a prescription for Actiq for this fentanyl-based opioid narcotic would typically include how many of these lollipop-type units?
MR. JAMES: Calls for speculation.
BY MR. CARTMELL:
Q. Do you know?
A. It depends on the prescription.
Q. Now, this depiction, it looks like, at the top has six different units of Actiq with numbers below them. For example, the top one has 200 mcg's. What is that?
A. The dosage strength.
Q. So, for example, the lowest dosage strength, is that true, would be 200 micrograms at the top?
A. Yes.

Q. And then if you go down, there was actually a strength of 400 micrograms, 600 micrograms, 800 micrograms, 1200 micrograms, and 1600 micrograms; is that correct?
A. Yes, it is.
Q. Now, at the end of this stick that looks like -- or the end of the unit that goes in the mouth, what is that?
A. That's where the medication is located.
Q. And I've heard that -- is it sometimes referred to as a lozenge?
A. Yes, we refer to it as a lozenge on a handle.
Q. And so when you put that lozenge in your mouth, if you were a patient who's been prescribed this, how is it that this medication, this opioid narcotic medication, works?
MR. JAMES: Calls for speculation.
MR. CARTMELL: Strike that.
I will ask the question again.
Q. Now, when the patient, as depicted here, puts the lollipop end or the lozenge end of the unit in the mouth, what are they supposed to do so that they get the fentanyl opioid narcotic

medication?
A. They rub it between their cheek and their gum, and it's a transmucosal delivery system.
Q. And when you say "transmucosal," what does that mean?
A. It goes through the cheek and the gum to the bloodstream.
Q. Okay. And it's supposed to be, I think I've seen from documents, more rapid on-site -- or onset of the effect?
A. That is correct.
Q. So that's -- that's one of the advantages, I take it, that Cephalon would tell doctors would be that this is a rapid onset type of medication; correct?
MR. JAMES: Calls for speculation.
THE WITNESS: Because it's appropriate for the treatment of breakthrough cancer pain.
BY MR. CARTMELL:
Q. Now, this Actiq, fentanyl-based opioid medication, I think according to the records, was first approved by the FDA in 1998, or thereabouts; is that consistent with your memory?
A. Yes.
Q. Now, you didn't get to Cephalon until

2001. But was Cephalon already selling, promoting, and marketing Actiq when you arrived?
A. That's correct.
Q. And I think because Cephalon purchased another company called Anesta, who had originally been the company who developed and actually received or filed the NDA, the New Drug Application, with the FDA and had the drug approved, Cephalon purchased Anesta and started selling this drug Actiq sometime around 2001; is that consistent with your memory?
A. Yes.
Q. It was shortly before you arrived; is that correct?
A. That's correct.
Q. Let me ask you about the drug listed on the right. It looks like it's called Fentora; is that correct?
A. Yes.
Q. Now, is Fentora another fentanyl-based opioid narcotic?
A. Yes.
Q. And this drug Fentora, it doesn't look like it's a lollipop-looking lozenge. But it looks like if you look below the packages, there are

tablets; is that right?
A. That's correct.
Q. Now, there's a depiction of an individual who is putting the tablet in their mouth. That's a Fentora tablet; is that right?
A. Yes.
Q. And this was a depiction from a product piece that we received from Cephalon. Do you recognize this?
A. Yes.
Q. Okay. And tell the jury, if you will, how this tablet is supposed to be placed in the mouth so that the individual or the patient who gets the medication gets the fentanyl medication released.
A. It goes between the cheek and the gum.
Q. Okay. And so is it also transmucosal?
A. Yes, it is.
Q. And it also is supposed to give a very rapid onset of the medication; is that correct?
A. Yes.
Q. Now, these are both Class 2 narcotics; is that right?
A. Yes.

Q. And Class 2 narcotics are the most highly restricted narcotics in the United States; is that correct?
A. No.
Q. What's the most highly restricted?
A. Class 1.
MR. JAMES: Calls for -- calls for legal conclusion.
MR. CARTMELL: Okay. Let me start over. I will ask you again.
Q. Class 2 narcotics are regulated by the Drug Enforcement Administration; is that correct?
A. Yes.
Q. Okay. And there are restrictions placed on the sale of those types of medications; is that correct?
A. Yes.
Q. Okay. And these two drugs, Actiq and Fentora, were they sold by Cephalon at the same time while you were there?
A. Yes.
Q. Okay. Tell me if I'm right about this. Actiq was sold by Cephalon from sometime in 2001, and it continued to be sold even after it lost its exclusivity; correct?

A. That's correct.
Q. But at some point in 2006, Actiq was no longer promoted or marketed by Cephalon; is that correct?
A. That's correct.
Q. And at the time that Actiq lost its exclusivity or its patent protection, that's when, at approximately the same time, Fentora, the opioid narcotic in a tablet form, came to market; correct?
A. That's correct.
Q. In other words, the approval of Fentora by the FDA was at precisely the same time as the time that the company stopped promoting the Actiq product; fair?
A. I don't believe it to be a correct timing.
Q. But around the same time as each other; do you remember that?
A. Yes.
Q. Now, each of these medications, as you said, were a part of the pain portfolio at Cephalon; correct?
A. Yes.
Q. And each of these medications, during your time there, had a team that was responsible for

the marketing and promotion and sales of these medications, these opioid medications; correct?
A. Yes.
Q. And were you on the Actiq team during the time that Cephalon was promoting, selling, and marketing the drug Actiq?
A. I was not on the marketing team. But I worked with the marketing team.
Q. Were you -- did you consider yourself on the Actiq team?
A. Yes.
Q. And then starting in 2006, or prior to that time prelaunch of Fentora, were you on the Fentora team as well?
A. Yes.
Q. During the time that you were at Cephalon, did your job involve the marketing and promotion of Actiq?
A. No.
Q. Did your job involve the marketing and promotion of Fentora?
A. No.
Q. You said you worked, though, with the Marketing Department; is that correct?
A. That's correct.

Q. I want to try to give the jury some idea about your involvement with these two narcotic opioid products while you were at Cephalon. And it sounds like you were on -- or in the Public Relations Department for eight years and were involved with these products in some way; is that correct?
A. That's correct.
Q. Okay. And tell us what your involvement was. And I may follow up and ask you some questions, but tell the jury what your involvement was as the manager on the public relations team that was overseeing the Actiq team and the Fentora team.
A. I was responsible for public relations, media relations, as well as working with the advocacy community in some capacities to build relationships and also patient education materials that were disease awareness only.
Q. Okay. Let me follow up on that a little bit.
Now, I saw from your bio online on your LinkedIn page that you developed and implemented product-related public relations strategy; is that correct?
A. That's correct.

Q. And you did that for both of these opioid narcotics; correct?
A. That's correct.
Q. Okay. And did that involve, for example, messaging to various members of the public about these products?
MR. JAMES: Vague.
You can answer.
THE WITNESS: It -- it related to messaging having to do with the media, and through the media, that would have gotten to the public. And it also related to messages that were used in some outreach to the patient community.
BY MR. CARTMELL:
Q. Okay. And messaging. Tell us what messaging means. That's a sort of a PR type of word, isn't it?
A. Yes.
Q. What does it mean?
A. It means finding a way to appropriately describe what it is that you're trying to communicate.
Q. So you mentioned the media. And sometimes I saw from documents in your custodial file that you would actually be involved with providing

information about Actiq and Fentora to the media; correct?
A. That's correct.
Q. And sometimes you would be involved in what types of messages you would give the media about these products; correct?
A. That's correct.
Q. And, for example, sometimes you would be involved with giving the media messages about Actiq and Fentora related to what types of products they are; correct?
A. That's correct.
Q. And sometimes you would give the media information about Actiq and Fentora about what they could be used for; correct?
A. That is correct.
Q. And when we say "media," we're not talking only about television, for example, radio, for example, but we're also talking about the print media?
A. That's correct.
Q. So, for example, the Wall Street Journal or other AP types of newspapers, for example; correct?
A. That's correct.

Q. So a lot of your job, it looked like, or a big part of your job, included messaging with the media about these two narcotic opioid drugs; correct?
A. That's a portion of my job.
MR. JAMES: Misstates her testimony.
BY MR. CARTMELL:
Q. You can restate your answer, please.
A. It was a portion of my job.
Q. Now, the other things, it looks like from your documents, that you were involved with and you mentioned on your LinkedIn page is that you partnered with industry groups, patient groups, professional societies and key opinion leaders; correct?
A. That's correct.
Q. What do you mean when you partnered with those groups? What do you mean by that?
A. We developed -- we spoke about breakthrough pain, what breakthrough pain was. There was lack of awareness of the condition. So both breakthrough pain, breakthrough cancer pain, and what -- what the needs of those patient populations were.
Q. When you say you partnered with

industry groups, give the jury some idea of what an industry group in the pain community might be.
A. The primary industry group was a coalition called the Pain Care Coalition. It involved industry groups, patient advocacy organizations, and professional societies.
Q. So would that pain coalition, as you called it, involve multiple pharmaceutical companies in the industry?
A. That's correct.
Q. And so sometimes you would work with those industry groups on the messaging that would be given about, for example, opioids in general?
A. That's not correct.
Q. Let me ask you this, then. Would you sometimes be involved with that coalition related to, for example, as you mentioned, breakthrough pain and the messaging related to breakthrough pain?
A. To increase the understanding of breakthrough pain, yes.
Q. And then you also mentioned that part of your job in public relations, and as it related to these opioid narcotics, had to do with your partnering with patient groups; right?
A. That's correct.

Q. Now, one of the things, I think, that you would do is actually from time to time be involved with providing some type of pamphlets or brochures, or things like that, actually to patients?
A. That's not correct.
Q. Okay. Let me re-ask it. Actually, strike that.
When you would partner with patient groups about these opioid narcotic medications, what would you do typically? Tell the jury.
MR. JAMES: Misstates her testimony.
THE WITNESS: Can you clarify that question, please?
BY MR. CARTMELL:
Q. One of the things you would do during your time at Cephalon and during the time that you were in the Public Relations Department working with Fentora and Actiq, the opioid narcotics, was you would work with patient groups, for example; is that true?
A. That's true.
Q. Give the jury an example of what you mean when you say "a patient group."
A. A patient group are organizations that represent the interests of people with a

specific condition. And I worked with a number of groups in that regard.
Q. Okay. So patient groups aren't necessarily groups of patients who are taking these drugs, but patient groups are actually organizations; is that right?
A. That's correct.
Q. Give us the names of some of the patient group organizations that you work with and partnered with when you were dealing with the opioid narcotics at Cephalon.
A. Cancer Care; American Pain Foundation; American Chronic Pain Association; reflex Sympathetic Dystrophy Syndrome Association, were probably the primary ones.
Q. And these are organizations, I take it, pain-type of organizations, that provide materials, literature, maybe information on websites to actual patients about opioid drugs?
MR. JAMES: Calls for speculation.
THE WITNESS: To some extent.
BY MR. CARTMELL:
Q. Okay. And those patient groups that you just mentioned, the American Pain Foundation, American Chronic Pain Association, those types of

pain -- or excuse me, patient groups, during the time that you were working with PR at Cephalon, Cephalon would provide those companies what are called grants from time to time; correct?

A. Those not-for-profits did receive grants from Cephalon.

Q. In other words, Cephalon would pay amounts of money to those groups from time to time related to providing information to patients about, for example, breakthrough pain or opioid information in general; correct?

MR. JAMES: Vague and ambiguous.

THE WITNESS: We would provide grants that were unrestricted to them to create the materials themselves.

BY MR. CARTMELL:

Q. I understand. But the American Pain Foundation, the American Chronic Pain Association, and the other patient-type groups that you dealt with in PR, they might come to you and Cephalon and ask for money; correct?

A. For grants, yes.

Q. Right. And then you had to decide what money or what grants you wanted Cephalon -- or Cephalon had to decide what grants or what money they

wanted to provide to those patient groups; correct?

A. In collaboration with a cross-functional committee.

Q. And that cross-functional committee included marketing; didn't it?

A. No. It actually did not, to the best of my memory.

Q. Your belief is that the Marketing Department was not involved in what grants were provided to patient groups?

A. They were not on the committee.

Q. Were they involved?

MR. JAMES: Vague.

THE WITNESS: They were involved to the extent that they were informed about possible opportunities to work with organizations.

BY MR. CARTMELL:

Q. And the grants or the money that you would provide to these pain foundations and patient groups, as you described, lots of times that money would go into written materials that they would produce for patients; correct?

A. That's correct.

Q. And those written materials that they would produce, for example, would include information

about the treatment of pain with opioids; correct?

MR. JAMES: Vague.

THE WITNESS: They included information about the treatment of opioids. They included information about the -- to build awareness about what breakthrough pain and what breakthrough cancer pain was.

BY MR. CARTMELL:

Q. You just mentioned two things -- right? -- breakthrough pain and breakthrough cancer pain. We're going to be talking about that today quite a bit. But those are two different things; correct?

MR. JAMES: Vague.

THE WITNESS: Two different patient populations. The same thing.

BY MR. CARTMELL:

Q. Okay. In other words, there are certain patients who have chronic pain that is not cancer related that have breakthrough pain; right?

A. That is correct.

Q. And then there are a separate group of patients that have cancer and can have breakthrough pain; correct?

A. That's correct.

Q. And your point is, those are two separate things, but the pain is the same; correct?

MR. JAMES: Misstates her testimony.

THE WITNESS: It doesn't state my testimony.

BY MR. CARTMELL:

Q. Explain again what you meant by that.

A. There are different underlying medical conditions that can lead to breakthrough pain.

Q. Okay. And one condition is cancer; right?

A. One condition is cancer.

Q. Other conditions might be things like back pain; right?

A. That's correct.

Q. Arthritis?

A. Possibly.

Q. What other types of conditions?

A. Certain neuropathic pain conditions.

Q. Okay. You also partnered with professional societies when you were working with these opioid narcotics, Actiq and Fentora. Tell us what you mean when you say a "professional society."

A. Organizations that represent health-care professionals, either doctors, nurses,

and the like.
Q. So these are societies that are actually made up of physicians or nurses?
A. That's correct.
Q. And these societies, when you would partner with them, tell us what you mean by that, and why would you partner with them about these opioid products?
A. I worked primarily with the leadership of those organizations to better understand their perspective on breakthrough cancer pain, breakthrough pain in general, and what the needs of the patient population were.
Q. I see. And tell us the names of some of those societies, those professional societies, that you worked closely with.
A. The American Academy of Pain Medicine; American Pain Society; American Academy of Pain Management; American Society of Pain Management Nursing.
Q. What about, for example, an anesthesiology professional society?
A. I did not work with them.
Q. What about a professional -- strike that.

Any other professional societies that you can remember working with related to the opioids Actiq and Fentora?
A. We had some outreach to the American Society of Clinical Oncology.
Q. Okay. And then finally you, in your job in PR related to Actiq and Fentora, the narcotic opioids, would partner sometimes with what you would call key opinion leaders; correct?
A. That's correct.
Q. Tell the jury what you mean when you refer to someone as a key opinion leader.
A. Somebody who is recognized as a prominent leader by their colleagues.
Q. And when you were working with these key opinion leaders, you were -- I take it they were typically doctors or nurses?
A. That's correct.
Q. In other words, a key opinion leader that is a doctor, that's somebody the company works with and may hire as a consultant; correct?
A. In some circumstances.
Q. And when the company might hire a key opinion leader as a consultant, they would pay that consultant for their time; is that right?

A. That's correct.
Q. Sometimes they would pay that consultant pursuant to an agreement on -- based on the actual activity that the consultant is performing; correct?
MR. JAMES: Vague. Calls for a legal conclusion.
THE WITNESS: I don't understand the question.
BY MR. CARTMELL:
Q. Well, for example, sometimes the -- Cephalon, the company, and you in PR, might partner with key opinion leaders to -- to write potentially manuscripts, for example; correct?
A. Independent of the company.
Q. I understand. But Cephalon may pay the individual --
A. Not an individual. You would not pay an individual to do a manuscript unless they were working on a -- something scientific related to our clinical trial program and they were investigators.
Q. Okay. That's a good point. We will distinguish that.
First, let me ask you this, though: Were there times that you would pay an organization a

grant that would then be utilized by key opinion leaders to, for example, write materials related to a disease condition or opioids?
A. That's correct.
Q. Okay. In other words, the company and you had control of the budget for a period of time for PR; correct?
A. That's correct.
Q. You might decide that you wanted to give a grant or money to an organization knowing that that money may go to a doctor, a key opinion leader, who would then write materials related to, for example, opioids or a disease state like breakthrough pain; correct?
A. No, that's not correct.
Q. What was wrong with what I just said?
A. The money went to organizations, not individual physicians, for the work that I worked on.
Q. Right. And that's -- I thought I made that clear. I think my question was this, but let me restate it.
From time to time you would decide, as the manager in the Public Relations Department, to pay money to an organization that the company knew, Cephalon knew and you knew, would then provide that

money to a key opinion leader or a doctor who would use that money either to speak or write information related to opioids or a disease state related to pain; correct?

A. Not -- not in my responsibility. My responsibility, individual physicians, to the best of my knowledge, were not paid by the organizations. Monies that we gave through grants went to the organizations.

Q. I understand. But is it -- are you --

A. It's not common practice for them, in turn, to pay a physician to do that work.

Q. Do you know if they did?

MR. JAMES: Calls for speculation.

THE WITNESS: Not to my knowledge.

BY MR. CARTMELL:

Q. Some of your work in the Public Relations Department, as you were a manager and overseeing these opioid medications, Actiq and Fentora, involved hiring key opinion leaders; is that correct?

MR. JAMES: Vague.

THE WITNESS: I'm not sure what you mean by "hiring."

MR. CARTMELL: Let me restate it.

Q. Some of your work in the Public Relations Department and working with the Actiq and Fentora involved you entering into consultant agreements and paying physicians to speak on certain topics; is that right?

A. In my role I only worked with -- in a consulting capacity with nurses.

Q. So then in your role, is it fair to say that some of your work in the Public Relations Department related to Actiq and Fentora would be that you would enter into consulting relationships and pay nurses to speak on certain issues?

A. Not to speak. We entered into agreements to be on an advisory board. They were not speakers under my responsibilities.

Q. So is it true that your company, Cephalon, would actually enter into consulting agreements with nurses across the country and pay those nurses to be a member of an advisory board for Cephalon?

MR. JAMES: Misstates her testimony.

THE WITNESS: Can you -- can you repeat that?

///

BY MR. CARTMELL:

Q. Is it true that Cephalon would from time to time and you, as PR manager related to the opioids, would enter into consulting agreements with nurses across America to be on an advisory board?

A. That's correct.

Q. And that the payment that would come from those agreements to the nurses would be for them to attend meetings and discuss topics related to opioids; is that correct?

A. Related to opioid medications for -- that were approved for breakthrough cancer pain.

Q. Have you been in the pharmaceutical industry -- strike that.

Have you been in the pharmaceutical industry for more than 30 years?

A. No. Since 2001.

Q. Okay. So you have -- so you've been in the industry for approximately 18 years; is that correct?

A. That's correct.

Q. And as someone with 18 years of experience in public relations and other areas in the pharmaceutical industry, I take it that you understand that PR and promotional and marketing

messages about your company's products, or Cephalon's products, should be true and accurate; fair?

A. That's correct.

Q. And I take it, as someone with approximately 18 years of experience in public relations and other areas in the pharmaceutical industry, you understand that public relations and promotional and marketing messages about Cephalon's products, for example, must be legal; correct?

MR. JAMES: Calls for a legal conclusion. Vague.

THE WITNESS: Can you restate what you're trying to get at?

BY MR. CARTMELL:

Q. Well, I'm -- I take it that during your approximately 18 years in the pharmaceutical industry, someone has told you that there are laws that apply to promotional messages, marketing messages, public relations messages, to media related to products; correct?

A. That's correct.

Q. And you know that from your experience in the industry; correct?

A. That's correct.

Q. And as someone with 18 years of

experience, I take it you know that there are laws and regulations that establish what a company like Cephalon can legally say and what it can't legally say related to products like these opioid products?

MR. JAMES: Calls for a legal conclusion.

THE WITNESS: I am aware of the laws. I'm not an expert because I'm not a lawyer.

BY MR. CARTMELL:

Q. I understand. But you have to be aware of those laws because your position, for example, at Cephalon with respect to these opioids was one that you were going to be making statements to the media and to the people in general about the products; correct?

A. That's correct.

Q. And I take it you recognize that it's important in your position to have a general understanding of what those laws are; correct?

A. That's correct.

Q. And I take it that you understand that you need to know what the law does and does not permit a drug company to say in terms of marketing and promotional messages about drugs like these opioid drugs; correct?

A. That's correct.

Q. I take it from being in the industry for -- strike that.

I take it that since you've been in the industry for apparently a little more than 18 years, you're aware of the Food, Drug, and Cosmetic Act; correct?

A. Yes.

Q. And I take it that when -- strike it, please.

I take it that you understand that when a drug like these drugs we're looking at, Actiq and Fentora, is approved by the FDA for sale on the open market, the FDA approves them for a specific indication; is that fair?

A. That's correct.

Q. Okay. And an indication means the FDA is saying what they have decided the drug is safe and effective to be used for; correct?

MR. JAMES: Calls for speculation. Calls for a legal conclusion.

THE WITNESS: That's my understanding, yes.

BY MR. CARTMELL:

Q. And so these two drugs, for example, Actiq and Fentora, the two opioid narcotics that you were responsible for overseeing as a manager of PR at

Cephalon, both of those drugs were approved for a certain indication? In other words, the FDA said those opioid narcotic drugs can be used for certain -- certain conditions; correct?

MR. JAMES: Calls for a legal conclusion.

THE WITNESS: They are approved for breakthrough cancer pain in opioid-tolerant patients.

(Exhibit No. 2 was marked.)

BY MR. CARTMELL:

Q. Let me hand you what's been marked as Exhibit 2, Ms. Beckhardt. And just asking, you have seen, I take it, the approval letters on both Actiq and Fentora; is that fair?

A. Some of them. Not all of them.

Q. In other words, you have seen some of the FDA materials that told the company Cephalon what it was approving Actiq and Fentora for; correct?

A. Correct.

Q. Okay. And this is a statement in general, I think, of basically what you just said. But both Actiq and Fentora were approved and only indicated for breakthrough cancer pain in patients with cancer who are already tolerant to opioid therapy for their underlying cancer pain; correct?

A. Correct.

Q. And that's a long way of saying that the FDA approved Actiq and Fentora for treatment only in cancer patients; correct?

MR. JAMES: Calls for a legal conclusion. Calls for speculation.

THE WITNESS: That's reflective of the -- of the indication.

BY MR. CARTMELL:

Q. Right. And so it had to be cancer patients that were getting these drugs -- there were some other requirements; right? The cancer patients had to be opioid tolerant, for example; right?

MR. JAMES: Calls for a legal conclusion.

THE WITNESS: It was critical that the patients be opioid tolerant.

BY MR. CARTMELL:

Q. And another requirement was, it was critical that the patients being treated with these highly potent opioid narcotics had breakthrough cancer pain; correct?

MR. JAMES: Calls for a legal conclusion.

THE WITNESS: That is the indication.

BY MR. CARTMELL:

Q. Okay. In other words, you testified previously there is one type of breakthrough pain

that is cancer pain, and there's another type of breakthrough pain that comes from other conditions like back pain, for instance; correct?

A. I think that misrepresents what I said. Breakthrough pain is a singular condition. What is different is the underlying cause of that pain.

Q. I understand that. And I'm not trying to be controversial. But I think what you're saying is one underlying cause of breakthrough pain is -- can be cancer, and then there are other underlying causes of breakthrough pain as well; correct?

A. That's correct.

Q. The FDA only approved Actiq and Fentora for the breakthrough pain with an underlying cause of cancer; correct?

A. Correct.

Q. And so once approved with the indication, as in the case of Actiq and Fentora, you understand, I take it from your 18 years of experience in the pharmaceutical industry, that Cephalon could not market or promote Actiq or Fentora for so-called off-label uses; correct?

A. That's correct.

Q. And off-label uses are uses of Actiq or Fentora that were not approved by the FDA; correct?

A. Yes.

Q. And did you have an understanding, from your time in the pharmaceutical -- excuse me, industry, that pharmaceutical companies can undermine the approval process if they promote drugs for uses for which they have not been proven to be safe and effective; would you agree with that?

MR. JAMES: Vague.

THE WITNESS: I'm not sure what you mean.

BY MR. CARTMELL:

Q. Let me ask you again. Would you agree that pharmaceutical companies can undermine the drug approval process by promoting drugs for uses for which they have not been proven to be safe and effective?

MR. JAMES: Calls for speculation. Vague.

THE WITNESS: I -- I don't know what you mean by "undermine the approval process."

BY MR. CARTMELL:

Q. You don't know what that means?

A. No, I don't. Because I don't see the connection between the two.

Q. Let me ask you this: Why is it that drug companies, once drugs like Actiq and Fentora are approved, are not allowed to market or promote for off-label uses?

MR. JAMES: Calls for speculation. Calls for a legal conclusion.

THE WITNESS: I'm not a lawyer.

BY MR. CARTMELL:

Q. Nobody has ever told you why -- once a drug like Actiq or Fentora is approved for an indication like for breakthrough cancer pain, nobody has ever told you why the company can't then go out and promote it for off-label uses?

A. Because promoting within the label is what is consistent with the regulation.

Q. And promoting within the label is consistent with the -- with what the FDA said was safe and effective for the drug; correct?

MR. JAMES: Calls for a legal conclusion. Calls for speculation.

THE WITNESS: A label is -- relates to safety and efficacy based on the data that were available at the time of approval.

BY MR. CARTMELL:

Q. Right. So, for example, with Actiq

and Fentora, there was never any data, when they were approved, given to the FDA to look at to determine whether or not those drugs were safe and effective in any conditions other than for breakthrough pain in cancer; correct?

MR. JAMES: Calls for speculation.

THE WITNESS: I wasn't there when the Actiq trials were conducted.

BY MR. CARTMELL:

Q. But you know that from your experience, almost eight, nine years' experience in public relations working at Cephalon with these drugs; correct?

MR. JAMES: Calls for speculation.

THE WITNESS: The original trials that were conducted were in cancer patients, but there were ongoing clinical trials that were in other patient populations.

BY MR. CARTMELL:

Q. I understand. But you just made the point that the reason the company needs to only promote and market products for what the FDA has said is safe and effective and the proper indication is because the FDA has looked at trials, studies in that indication; right?

MR. JAMES: Misstates her testimony. Calls for speculation.

THE WITNESS: There are many instances where FDA has approved drugs, to my understanding, that are based on one data set and have given them a broader or narrower indication.

BY MR. CARTMELL:

Q. Do you know whether or not the FDA ever considered any studies or data when it approved Actiq and Fentora for breakthrough cancer pain? Do you know whether they considered any studies or data outside of the cancer arena? Do you know?

A. In the original application?

Q. Yes.

A. Not to my knowledge.

Q. Okay.

MR. JAMES: We have been going about an hour.

MR. CARTMELL: Let's take a break.

MR. JAMES: Take a break.

THE VIDEOGRAPHER: We are going off the record. The time is 10:36 a m.

(Recess taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 10:52 a m.

BY MR. CARTMELL:

Q. We are back on the record after a short break. Are you ready to proceed?

A. Yes.

Q. Ms. Beckhardt, you mentioned previously that sometimes your job in the PR Department at Cephalon would involve delivering messages to the media, either paper or television or radio, related to the Actiq and Fentora opioid products; correct?

A. That's correct.

Q. Now -- and I noticed from the documents that were produced by Cephalon and Teva in this lawsuit, that oftentimes you were a spokesperson for Cephalon related to the opioid narcotic drugs; correct?

A. That's correct.

Q. In other words, you were one of the individuals within the company that when a reporter might call the company or a writer for a paper, things like that, you were one of the people who might respond to that request for information for the company; correct?

A. Yes.

Q. And -- and I noticed that in some of

the documents, there was reference to being media trained. Do you know what that means?

A. Yes, I know what that means.

Q. And tell the jury what "media trained" means.

A. It means preparing an individual who is going to speak to the media so that they understand and can expect -- know what to expect and can articulate messages in a way that's consistent with the truth.

Q. Okay. And it's important that it be the truth; correct?

A. Absolutely.

Q. In other words, when you're giving those messages, you want them to be truthful and accurate; correct?

A. Yes.

Q. Okay. And were you one of the people for the company that would oftentimes train other individuals, managers, senior executives, things like that, on speaking to media?

A. There were occasions that I did that.

Q. Okay. And you did that on occasions when they would respond to the media about the opioid products; is that correct?

A. Yes.

Q. Okay. Now, we talked about your job responsibilities. And I noticed from the documents that every single year, you put together a plan, a PR plan or strategy, related to the opioid drugs; correct?

A. Yes.

Q. Okay. In other words, you had a strategy from a public relations standpoint on PR activities and tactics that you would use on a yearly basis; correct?

A. That we would propose to use.

Q. And you would propose these tactics and a strategy from a PR perspective to who?

A. To others within the Public Relations Department as well as the Marketing Department.

Q. Okay. And that's what I was going to ask you. You said you don't work within the Marketing Department, but you work with the Marketing Department; right?

A. That's correct.

Q. And so when you would put together your public relations strategy on the messages and tactics related to the opioids Actiq and Fentora, would that then -- that strategy and your proposed

messages and tactics, would that then have to be approved by the Marketing Department?

A. Not the messages.

Q. Okay. But the strategy and the tactics that you would use?

A. The general strategy, the general approach would be approved, but not necessarily the specifics of how those strategies were implemented.

Q. I didn't ask you this, but you were a manager in the Public Relations Department when you were hired in 2001; is that correct?

A. I was a Senior Manager.

Q. Okay. And at all times you remained in senior management; is that correct?

A. Senior Manager is not a senior management position. I was promoted to Associate Director.

Q. Okay. And I apologize, but really all I was getting at is that you were managing others within the PR Department at all times while you were --

A. I did not have any direct reports.

Q. Did you ever have direct reports while you were at Cephalon and working with Actiq and Fentora?

A. No.

Q. I want to move on and talk more about your involvement with Actiq and Fentora. But before we do that, I want to make sure you understand that you're here today testifying under oath in a lawsuit that has been filed by municipalities, including cities and counties and some states, against drug manufacturers, including your former employees -- employers, Cephalon and Teva; do you understand that?

A. Yes.

Q. And I want to make sure you understand the claim that's being made in this case. You understand, I take it, that municipalities across the country in this case are claiming that Cephalon and Teva, along with other drug manufacturing companies that manufacture opioid products, the claim is that they contributed to an opioid epidemic in this country by unlawfully marketing, promoting, and selling, in Cephalon's case, Actiq and Fentora to doctors and patients, and that the illegal, unlawful marketing resulted in significant overuse of Actiq and Fentora. Do you understand that?

MR. JAMES: Calls for speculation. Assumes facts not in evidence.

THE WITNESS: I've -- I've not read the

claim, so -- so myself.

BY MR. CARTMELL:

Q. And I just want to make sure you understand, before we get deeper into this, the claim. So let me state it and ask you if you understand.

Do you understand that in this lawsuit that municipalities from across the country in this case are claiming that Cephalon and Teva contributed to an opioid epidemic in this country by unlawfully marketing, promoting, and selling Actiq and Fentora to doctors and patients, and that the illegal, unlawful marketing resulted in the significant overuse of those opioid medications? Do you understand that?

MR. JAMES: Calls for speculation.

THE WITNESS: I understand what you are saying is the claim.

BY MR. CARTMELL:

Q. But you've never looked at any of the pleadings in this case, the complaint, or what the specific claims are?

A. No, I have not.

Q. And you've never been told before I just told you what the specific claims are; is that

right?

A. Not in that detail, no.

Q. Okay. And let me ask you, do you believe, as you sit here today under oath, that there is a prescription drug opioid epidemic in this country?

A. Yes.

Q. And do you believe that that opioid epidemic has gone on for sometime now, several years?

A. That's correct.

MR. JAMES: Vague.

BY MR. CARTMELL:

Q. And I take it that during the time that you were at Cephalon, you started to develop that understanding; is that fair?

A. Yes.

Q. Okay. And do you have personal experience with this opioid epidemic? In other words, has this prescription drug opioid epidemic affected you or your family?

A. No, it has not.

Q. You don't have any family members or friends that it's affected?

A. No.

Q. Have you done any research or talking

to any experts about the opioid epidemic, the prescription drug opioid epidemic before today?

MR. JAMES: Vague.

THE WITNESS: At what point in time are you speaking about?

BY MR. CARTMELL:

Q. Any time before today.

A. Yes.

Q. What type of research have you done related to this prescription drug opioid epidemic?

A. I have not personally done research. I've read research, and I've talked to investigators who conducted that research who were experts in the field of addiction.

Q. Okay. Let me tell you this, too, because I want you to understand the claim and what -- or what the claim in this lawsuit is with respect to the damage that the drug companies have caused from contributing to the opioid epidemic. So let me ask you if you understand this.

Do you understand that the claim is that because of Cephalon and Teva's unlawful marketing and promotional tactics caused the significant overuse of Actiq and Fentora, there was a dramatic increase in the abuse, misuse, and diversion of these drugs,

leading to increased addiction, death, overdoses, and huge societal costs related to these things? Do you understand that that is the claim in this case?

MR. JAMES: Assumes --

A. I understand that is the claim.

MR. JAMES: Assumes facts not in evidence. Calls for speculation.

BY MR. CARTMELL:

Q. You can answer. Just state it again, because I think you guys were talking over each other.

Go ahead and repeat.

A. I understand that that is the claim, as you have stated it.

Q. Okay. And, lastly, do you understand that you're here today and we've asked to take your deposition because you were at Cephalon during those approximately ten years during the period of time that the Fentora and Actiq opioid drugs were being promoted and marketed by the Marketing Department, and you were in the Public Relations Department at that time? Do you understand that?

A. Yes.

Q. Now, we talked about when you arrived in 2001, Actiq was already being sold and marketed by

Cephalon at that time; is that right?

A. Yes.

Q. And I take it when you arrived at the company, you had to in some respects sort of dig in and get up to speed on the drug, the opioid narcotic Actiq, that was being sold at that time; is that fair?

A. That's correct.

Q. In other words, you probably had to go back and look at the documents to try to educate yourself on what Actiq is as a drug and the potential risks associated with that drug; is that fair?

A. I'm not sure what documents you would be referring to.

Q. I'm just asking you, Ms. Beckhardt, in general, when you arrived as a new employee at Cephalon, whether you did some investigation and research to try to determine what the risks, for example, of Actiq, the opioid narcotic that was being sold at that time by Cephalon?

A. I was familiar and read information from the label of the product.

Q. When you arrived in 2001 at Cephalon, had you ever worked with, in any capacity, a fentanyl opioid narcotic before?

A. No.

Q. Had you worked, though, prior to coming to Cephalon, with any opioid medication?

A. I have never -- I have never worked with a medication before.

Q. So your experience at Cephalon in 2001, this was the first time you had actually worked in a pharmaceutical company related to a medication -- any medication, much less an opioid medication; fair?

A. That's correct.

Q. Now, do you have knowledge, you think today, about the dangers associated with a highly potent fentanyl narcotic opioid like Actiq and Fentora?

MR. JAMES: Calls for speculation.

THE WITNESS: I'm not sure what you mean by "dangers." That's a very broad term.

BY MR. CARTMELL:

Q. Do you believe that there are dangers associated with Actiq and Fentora?

MR. JAMES: Vague.

THE WITNESS: The primary risk with Actiq and Fentora related to the use in nonopioid-tolerant patients.

BY MR. CARTMELL:
Q. And what risk was it that you're referring to?
A. The potential -- potential for respiratory depression in nonopioid-tolerant patients.
Q. And when you say "nonopioid-tolerant patients," I've seen documentation that that refers to patients who had not been on chronic or longer-term opioid treatment; is that right?
A. No, that's not correct.
Q. What does it mean?
A. It means that patients are currently on long-term, around-the-clock opioid medication.
Q. Was there an understanding you had about how long a patient needed to be on around-the-clock opioid medications prior to starting the Fentora or Actiq?
A. I do not believe that was referenced in the label.
Q. So, as far as you knew, the only requirement was that the patient needed to be currently on around-the-clock opioids to start the subsequent opioid Fentora or Actiq; correct?
MR. JAMES: Misstates her testimony.

THE WITNESS: Patients prescribed a -- a medication for breakthrough pain should be on an around-the-clock opioid simultaneously.
BY MR. CARTMELL:
Q. I guess my question was: How long did they need to be on a simultaneous around-the-clock pain medication before you could start them on Actiq or Fentora, or do you know?
A. I'm not a clinician. I can't speak to that.
Q. When you started at Cephalon in 2001, were you in a department or were you on a team called the Diversion Team?
A. Yes.
Q. Tell the jury what the Diversion Team was.
A. The Diversion Team was intended to monitor instances of diversion of the product and to determine if there was a problem that needed follow-up.
Q. Okay. So when you said diversion, though, are you referring to instances when the company would be informed about one of their products, either Actiq or Fentora, being diverted outside of appropriate uses and taken by somebody who

wasn't prescribed?
A. I'm referring specifically to somebody taking a -- using a medication for whom it was not prescribed.
Q. Okay. And so as a member of the Diversion Team, whenever there were instances reported to the company about the diversion, for example, of Actiq starting in 2001, you would be on the team that would be notified about that; is that right?
A. That's correct.
Q. And shortly after you started at Cephalon, I take it you started learning that the Actiq product was from time to time being diverted; is that right?
MR. JAMES: Vague.
THE WITNESS: I don't know what you mean by "from time to time."
(Exhibit No. 3 was marked.)
BY MR. CARTMELL:
Q. I've handed you Exhibit 3. Why don't we just look at this email string, if you don't mind, that was produced to us from the internal files of Teva in this case. And I want to ask you a few questions about this, Ms. Beckhardt.

If you look at the first page, Ms. Beckhardt, this is an email from you to several other employees at Cephalon back in November of 2003; is that right?
A. May I have an opportunity to look at the whole document, please?
Q. Sure.
MR. RIGBERG: This is Karen Rigberg, of Arnold & Porter. Is there a Bates number for this exhibit?
MR. CARTMELL: TEVAMDL03316708.
MR. RIGBERG: Thank you.
BY MR. CARTMELL:
Q. Ms. Beckhardt, this internal document is an email from you to several other employees at Cephalon in November back in 2003; is that correct?
A. That's correct.
Q. And the subject matter is "Actiq Investigation Segment on Channel 6 News." Do you see that?
A. Yes.
Q. You state:
(Reading) I wanted to provide a quick update to the local media story on Actiq last week. To date we have

received no additional inquiries from the media regarding this incident (end of reading.

Now, let me ask you real quick: Were you one of the employees or the employee at Cephalon who was in charge of sort of monitoring the inquiries from the media about Actiq?

A. I monitored. We also took reports from other employees. I also had a public relations agency that monitored media.

Q. Okay. It states:

(Reading) We have been in contact with the local police department to determine whether or not they had lot numbers for the seized property (end of reading.

And then it states:

(Reading) Their interest in learning more about Actiq should not be interpreted as a signal that they believe there's a large problem in Philadelphia; rather, they wish to be more proactive in their efforts than they were with Oxycontin (end of reading.

Do you see that?

A. Yes.

Q. I take it you learned, when you got to Cephalon and started working in this industry with these types of narcotic opioid drugs, that there had been a problem in the past with a drug manufactured by another drug manufacturer called Purdue and with diversion of that product; is that correct?

A. I'm aware of it. It was not our product.

Q. And -- but at any rate, you knew that another opioid at least, OxyContin, over the years previously there had been large quantities of that drug diverted, frankly, to the streets of America; did you learn that?

MR. JAMES: Calls for speculation. Assumes facts not in evidence.

MR. CARTMELL: You can answer.

THE WITNESS: We had 0.2 percent of the marketplace. We were indicated for a very narrow usage. And it was not a comparable situation.

MR. CARTMELL: Okay. I'm going to object and move to strike that answer because it wasn't responsive, and I will ask the other one again and give you a chance to answer.

Q. But at any rate, you knew that another opioid, OxyContin, over the years previously, there had been large quantities of that drug diverted to the streets of America? You learned that; correct?

MR. JAMES: Same objections.

THE WITNESS: I don't know how to quantify "large quantities" because it was not my product.

BY MR. CARTMELL:

Q. I understand. But at any rate, you learned that it was happening around America?

A. I learned that there was some diversion of Oxycontin.

Q. Okay. Now, I want to go to the next page. And there was actually an article or an Action News exclusive, it looks like it's called -- attached by you and sent around to several individuals, I believe. Or actually it was attached by a Cheryl Williams?

A. That's correct.

Q. Okay. Who was Cheryl Williams?

A. She was my -- at that time she would have been my boss.

Q. Okay. The title of this piece is, "Heard the New Buzz on the Streets?" Do you see

that?

A. Yes.

Q. (Reading) November 20, 2003:

This is a Perc-O-Pop, the newest drug to hit the streets of Philadelphia (end of reading).

Now, Perc-O-Pop, I take it that was a name for Actiq on the streets that I suspect you became familiar with; is that fair?

A. Yes.

Q. Okay. And the reason, I take it, for that name Perc-O-Pop, was that as we saw previously from the depiction of Actiq, it sort of looks like a lollipop? In other words, it has a stick and a lozenge on the top of the stick; correct?

A. That's correct.

MR. JAMES: Calls for speculation.

BY MR. CARTMELL:

Q. You can answer.

A. I don't -- it is true that that's a description of the product. But I don't know how the street name came. You know, I'm not on the street.

Q. Okay. I understand that.

You answered, though, "That is correct." Then your lawyer objected.

A. Well, it's correct that I was aware Perc-O-Pop was used on the streets.

MR. CARTMELL: And just for you, you're supposed to object to the form and not coach the witness.

MR. JAMES: I'm not trying to coach the witness.

MR. CARTMELL: So, believe me, we're a hundred percent good with you objecting to the form. And then if we need to take it up, you're not waiving anything, you can take it up later.

MR. JAMES: Okay.

Q. Okay. It then states:

(Reading) this is the first time the narcotics unit has come across them. A Perc-O-Pop is actually oral transmucosal fentanyl citrate. It's sold under the brand name Actiq and sold to cancer patients who suck on the sticks to relieve intense pain. Now police say it's being stolen and sold illegally (end of reading).

Correct? That's what it says?

A. That's what it says.

Q. I take it, after you had worked there

for a period of time, you began to get reports like this of your Actiq product being diverted onto the streets across America; correct?

A. We had a limited number of reports.

Q. Okay. (Reading) Investigators tell Action News just last month a young female offered to sell undercover agents Perc-O-Pops for $20 each (end of reading).

And you learned also, I take it, Ms. Beckhardt, that Actiq started to have what's oftentimes called street value; correct?

A. Yes.

Q. It states:

(Reading) We saw her make several deliveries. At one in particular, there were three girls in front of a Wawa, and I think their average age was 16 to 20 years old. Just this past week, police raided their suspect's Bucks County home and turned up piles of Perc-O-Pops, cash, and other drug paraphernalia. We had no trouble finding an 18-year-old familiar with Perc-O-Pops. They

freeze them and, like, suck them and get high off of it (end of reading).

Now, let me ask you: Was there a time, shortly after or during this period of time when you got reports of the Actiq drugs being diverted onto the streets, that it became apparent to you in PR, or the management of the company, that there was a certain interest in diversion of these types -- or this type of fentanyl drug because it looked like a lollipop and had a sweet taste?

A. I don't agree with that premise. We were aware of some diversions.

Q. And I take it you were also aware, were you not, that in several reports there were indications that, either from the authorities or from the individuals involved, that there was a certain interest in this product specifically because of the way it tasted sweet and looked like a lollipop? Did you ever hear that?

A. No.

Q. It states:

(Reading) If you don't know any better, a Perc-O-Pop just looks like a harmless lollipop. But the manufacturer's label warns Actiq can

be harmful, even fatal, to children and can cause injury or death to anyone who is not already using a prescription pain medication (end of reading).

And, Ms. Beckhardt, is that what you were talking about, is that this drug is potent and that it can cause death to individuals if it's diverted and taken -- if the individual is not already on an around-the-clock opioid? Is that what you were talking about?

A. That statement is not my statement. But when I said before, yes, there is a risk. There is a risk.

Q. And the risk is death; correct?

A. That is a risk factor.

Q. "Also they can be highly addictive." Do you agree with that, Actiq can be highly addictive?

A. I believe Actiq could be addictive in the -- in a patient population that is -- or a using population that is susceptible to addiction.

Q. It states:

(Reading) All reasons why the Narcotics Unit wants to make sure

police on the street and parents know they are out there. They are dangerous, and unfortunately they are getting into the hands of young people (end of reading).

Do you see that?

A. Yes.

Q. Now, do you remember in 2003, was there a period of time that Cephalon did anything to up their monitoring or change their policies related to the diversion of Actiq?

A. Well, as stated in the first page of this, we contacted the police.

Q. Okay. But other than contacting the police after an incident like this, was there any other changes to the monitoring, that you can recall, for diversion, abuse, or misuses that were done around this time in 2003 or 2004?

A. I don't recall the dates.

Q. But at any rate, from this report at least, your company and you were aware the town directly adjacent to where you were working, the police were saying that there was starting to be diversion of these Actiq lollipop-like fentanyl products, opioid products, onto the streets; correct?

MR. JAMES: Objection. Form.

THE WITNESS: Could you repeat that question, please?

BY MR. CARTMELL:

Q. At any rate, from this report at least, your company and you were aware that in the town, Philadelphia -- which was just adjacent to where you were working; correct?

A. Yes.

Q. And these were local reports, in other words, you were getting -- like this report is from a local TV station; is that correct?

A. That's correct.

Q. Okay. At least you knew at this time, Cephalon knew at this time, that there were reports of Actiq starting to be diverted into young people's hands on the streets in Philadelphia?

A. We were aware --

Q. Go ahead.

A. We were aware of what was in the media report, that there was a diversion in the city of Philadelphia.

Q. Okay. Well, you knew about more than one reported diversion; didn't you?

MR. JAMES: Vague.

THE WITNESS: Yes, I was aware of individual incidents, but they were -- I believe they were relatively small in number.

(Exhibit No. 4 was marked.)

BY MR. CARTMELL:

Q. Okay. I've handed you what's been marked as Exhibit 4.

A. Sorry.

MR. CARTMELL: Or excuse me, Exhibit 5.

MR. JAMES: I think it's 4. It's 4.

MR. CARTMELL: Sorry. 4?

THE WITNESS: Yes.

BY MR. CARTMELL:

Q. Now, Exhibit 5 [sic] is another internal email string that was produced in this lawsuit, and I want to ask you just real quick a question or two about this. But if you go to the bottom, there's an email from Victor Raczkowski.

Who is Mr. Raczkowski?

A. At the time he was the Vice President of Regulatory Affairs.

Q. So was he in senior management?

A. Yes.

Q. And he says:

(Reading) Folks, I just got a phone

call from a Cephalon employee letting me know that tonight Channel 6 News aired a segment about Actiq finding its way to the streets (end of reading).

And then it talks about -- on the next page it talks about and actually says that the piece showed a picture on the television of the Actiq product; correct?

A. Yes, that is correct.

Q. And he mentions here that -- it mentioned that the -- the piece mentioned that it was a morphine-like compound that's being diverted to the streets for illicit recreational use and finding its way into the hands of children.

Do you see that?

A. That's what Dr. Raczkowski said the media report said, yes.

Q. And let me ask you: Was that concerning to you in public relations, that these products were making their way into children's hands that were not opioid tolerant?

A. Of course. Any diversion is a concern.

Q. And then if you look at the first

page, there's a response, another email from a member of the senior management at Cephalon to several individuals, including Carol Marchione, who is Regulatory Affairs; is that correct?

A. That's correct.

Q. And it states:

(Reading) FYI, it looks like diversion of Actiq is becoming more of an issue (end of reading).

Do you see that?

A. Yes.

Q. And so this was a time period, in 2003, when the company knew that diversion of these highly potent products, Actiq, fentanyl opioid narcotics, and that this was a time when it was becoming more of an issue; correct?

MR. JAMES: Objection.

THE WITNESS: The Philadelphia diversion was the first large-scale diversion about which I was aware. So, yes, it was concerning. However, it was not a -- we did not have a large number of diversions prior to this, that I'm aware of.

(Exhibit No. 5 was marked.)

BY MR. CARTMELL:

Q. I am going to hand you what's been

marked as Exhibit 5, ask you a few questions about this.

And this is actually a report that was produced in this litigation from the files at Teva and includes a statement by you.

A. Yes.

Q. The title of this article in 2004, early 2004, April of 2004 is, "Increase in Abuse Reported of Narcotic Lollipops for Cancer Patients."

(Reading) a narcotic pain killer in lollipop-like form designed to speed relief to cancer patients has begun showing up in illegal sales in Philadelphia and elsewhere under the street name Perc-O-Pops (end of reading).

Do you see that?

A. I see what it states.

Q. If you skip down on the paragraph, it states:

(Reading) We are starting to see it emerge as a drug, that is, as we call it, diverted which is a legally prescribed drug being used illegally. And it's a drug that is easily

administered or taken by someone who might be afraid to either take a pill, snort, or inject a needle in their arm (end of reading).

Do you see that?

A. I see what it states.

Q. Did y'all have any conversations at any time that you can remember that potentially the product itself and the fact that it was a lollipop-looking product and the fact that it was made sweet and sugary, that that might increase the odds that it was actually a product that would be abused, misused, and diverted?

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. Or do you know?

A. I don't know. I understand why the product was made sweeter. But I don't know the answer to your question.

Q. If you skip down, there's a quote by you that states:

(Reading) Stacey Beckhardt says, "The company does not know the extent to which Actiq is used recreationally" (end of reading.)

Do you see that?

A. Yes.

Q. And this is an instance, for an example, when a media outlet reached out to the company, they asked you to respond; is that fair?

A. Yes.

Q. And what you're saying there is that actually you as a company didn't really know how often these products were being diverted; correct?

A. We knew what was reported to us.

Q. Right. And I guess that was going to be sort of my point, was that your company would only know about diversions if, in fact, the diversion of the Actiq product ended up on a news outlet or in the media or if it was reported to you; correct?

MR. JAMES: Objection.

THE WITNESS: We also knew of reports if they came from the police. But we were -- you know, we were a very small piece of the marketplace. So an increase of diversion was not necessarily a large-scale diversion.

BY MR. CARTMELL:

Q. Well, what do you call large-scale diversion?

A. We, to my memory, at this time had

had -- this was the largest diversion, the diversion in Philadelphia, and there were 40 units or so.

Q. And I understand what you're saying. But my point is, the company only knows about diversions that are in the media or reported to the company by a police officer or somebody else; fair?

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. In other words, the company can't know what it doesn't know; right?

A. Yes.

Q. But you knew, as a PR person and having worked with these drugs now for a period of time, that the company wasn't being reported all the diversions? In other words, there were more diversions out there on the streets and in the communities than were reported to your company; you knew that?

A. I did not know that.

Q. You didn't know that?

A. No.

Q. So your understanding, just so it's clear for the jury, was that every time there was a diversion of your product, your company knew about it; is that your understanding?

MR. JAMES: Objection.

THE WITNESS: You're misstating my testimony.

BY MR. CARTMELL:

Q. I'm not trying to be controversial, but I think you just said that you figured that every time there was a diversion, the company was going to find out about it, it would be reported?

A. That's not correct.

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. So then my point is simply this: You knew that there were diversions out in the communities and societies across America of your products that your company never heard about? You knew that; correct?

A. That's not true.

Q. I don't know why we're not communicating. It's probably my fault. But if you -- if you -- if that's not true, then what am I missing?

A. Because we weren't -- because we were not aware of them, we didn't know if there were other cases.

Q. I understand. But were you actually

thinking as a company that there potentially or possibly or likely were other diversions; that you just didn't find out about them?

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. Was that a possibility in your mind?

A. We took -- we took steps to mitigate all the diversions that we could.

Q. Okay. That's not my question. All -- I really am not trying to be controversial. I just want to know, did your company, Cephalon, think it was possible or entertained the thought potentially there were diversions happening that you weren't finding out about?

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. And maybe it's something you never thought about. That's fine.

A. It's -- it's not the way we addressed -- we focused on those that we were aware of and tried to do something about those that we were aware of.

Q. Okay. In other words, you waited until they were reported to you, and then you focused on those and investigated those in more depth;

correct?

A. That's not entirely true, because we had a Risk Management Program in place that allowed us to take some steps that ensured we were -- we had control of our product to the best of our ability. We had a very small portion of the marketplace and a very tight distribution system.

Q. It states on the next page:

(Reading) Philadelphia police arrested a Bensalem couple in October on drug charges and seized nearly 100 Perc-O-Pops (end of reading).

Do you see that?

A. Yes.

Q. I think you said a minute ago that you thought the largest one was 40?

A. I didn't recall this one.

Q. Okay. The 40 diversion was another one?

MR. JAMES: Objection. It appears to be a second diversion.

BY MR. CARTMELL:

Q. And would you agree with me that a hundred of these active lollipops on the streets, being given to children or others who are not opioid

tolerant and on an around-the-clock opioids, could be very dangerous? Do you agree with that?

MR. JAMES: Objection.

THE WITNESS: You're speculating who -- who the products were used by. We don't know that.

BY MR. CARTMELL:

Q. If they were given to children or people who were not opioid tolerant, do you agree that a hundred of those floating around the streets could be dangerous --

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. -- in Philadelphia or Bensalem?

MR. JAMES: Objection.

THE WITNESS: Any diversion is a concern.

BY MR. CARTMELL:

Q. It then states that:

(Reading) That raid was prompted by a prior arrest in northeast Philadelphia that netted about 30 of the Actiq lozenges (end of reading).

Do you see that?

A. Yes.

Q. So that's another diversion of 30?

A. No. That's the previous diversion.

Q. (Reading) Parley said each Actiq lozenge retails for $9.10, but the going street value is $20 (end of reading).

Do you see that?

A. Yes.

Q. And then it says:

(Reading) You don't want drug to taste good, particularly a narcotic pain killer that you don't want people to use for long periods of time, he said (end of reading.)

You agree with that?

A. He's not a clinician and does not understand why it was berry flavored.

Q. So you disagree with that?

A. Correct.

Q. At the bottom it states:

(Reading) Hospitals in the 48 contiguous states reported 576 incidents of nonmedical use of fentanyl products in 2000, but the number rose to 1506 by 2002 (end of reading).

Do you see that?

A. I see that.

Q. That's a tripling of the incidence in a two-year time frame, according to this; correct?

A. We do not believe those were our products. They were other fentanyl products on the marketplace.

Q. Okay. First, I just -- I want you to answer, that's a tripling, is it not, in a two-year period?

A. According to these statistics.

Q. And that was right in the time period when Actiq came to the market? In other words, Actiq came to the market in 2001; didn't it?

A. There were --

MR. JAMES: Objection.

You can answer.

THE WITNESS: It's true that there were -- simultaneously there were other fentanyl products on the market.

BY MR. CARTMELL:

Q. I understand that. Did y'all do anything at this time, when there had been nearly a hundred Perc-O-Pops diverted and another incident -- you said 30 -- and this was just in your hometown when you -- where you were getting local reports --

did you all do anything at this time to go out and further investigate potential diversions and abuse and misuse of Actiq that wasn't reported to your company?

A. That would not have been my responsibility.

MR. CARTMELL: I want to ask you if you agree with something that was stated by one of your colleagues in an email that we were given from your internal files. And I'm going to hand you Exhibit 6.

(Exhibit No. 6 was marked.)

MR. RIGBERG: Is there a Bates number for this document?

MR. CARTMELL: TEVAMDL03272549.

(Witness reviewing document.)

BY MR. CARTMELL:

Q. Now, Ms. Beckhardt, Exhibit 6 is an email that was sent by you to several other individuals at Cephalon in January of 2005; correct?

A. That's correct.

Q. And I want to start, like emails do, from the back page, if that's okay with you. And if you go to the second page, there's an email from you on the 24th of January to several other individuals. And some of those are in marketing; is that correct?

A. That's correct.
Q. Andy Pyfer, I see his name a lot. Was he the Senior Director of Marketing?
A. I don't remember his title. But he was the head of the team at that point.
Q. Head of the Actiq team?
A. Yes.
Q. From a marketing standpoint?
A. That's correct.
Q. You say, "FYI, a research letter in JAMA" -- that's a journal; is that right?
A. That's correct. A medical journal.
Q. -- "reported on increased reports of diversion and abuse of methadone." What is methadone?
A. Methadone is an opioid medication that's long-acting.
Q. Okay. And methadone, just so it's clear for the jury, is not a pharmaceutical or a drug that Cephalon manufactured or sold?
A. That's correct.
Q. Okay. But this is a -- is a -- strike that.
This is an article that was of interest to you, and so you felt like you should forward it on to

your colleagues; correct?
A. Because I kept my colleagues informed of the general -- the use of opioids inappropriately in the community.
Q. Right.
A. So that we were aware, and so that we would take appropriate actions internally.
Q. Okay. And this is -- I'm not going to go through this in detail, but this is stating that this -- there were increased reports of diversion and abuse of this other opioid, methadone.
Of interest, one of the researchers is James Inciardi and the research was supported by Purdue pharmaceuticals; correct?
A. According to this, yes.
Q. Okay. And this study just talks about there was a five-fold increase of diversion or abuse reports with methadone in 2003; correct?
A. That's what the article states.
Q. Okay. And methadone tablets were indicated in more than 80 percent of the reports of abuse and diversion, compared to wafer or liquid form generally dispensed by methadone clinics; do you see that?
A. Yes.

Q. Now -- and I take it over time you continued to get more and more reports of not just diversions with your drug Actiq that you were involved with in PR, but of other opioid products being diverted across America; correct?
A. That's correct.
Q. And here's another report of another opioid that had a five-fold increase during this period of time; correct?
A. It wasn't one of our products.
Q. I understand. But is it true that you still had interest, and it still was concerning to you even if it was another company's products, that were being diverted, if they were opioids; right?
A. It was important for us to know about it, yes.
Q. Okay. And then what I want to focus your attention on is on the first page, an email from Terrence Terifay that was on January 24th, 2005.
Do you see that?
A. Yes.
Q. And Terrence Terifay, I think, was a manager in the Marketing Department; is that right?
A. That's correct.

Q. And you had sent this to him, and he responds to the article, and he states:
(Reading) Interesting study. It makes complete sense, since pain physicians, hospitals, and managed care were pushing methadone use right after the Oxycontin explosion (end of reading).
And I want to refer you to the last sentence. He states:
(Reading) The bottom line is, as we all know, greater availability of a drug directly correlates to abuse and diversion (end of reading).
Do you see that?
A. Yes, I see that.
Q. And do you agree with that statement by your colleagues in management?
A. I think that generally that is true.
Q. Okay. In other words, especially with opioid drugs, would you agree with me that the more widely available they are, the more abuse and misuse and diversion you likely will have?
MR. JAMES: Objection.
THE WITNESS: I believe with any product, whether it's an opioid or not an opioid, if it -- if

there is an increase in usage, there's a potential for it to be used inappropriate. That's the condition for any medication.
BY MR. CARTMELL:
Q. Right. It's common sense; right?
MR. JAMES: Objection.
THE WITNESS: I can't speak to common sense.
BY MR. CARTMELL:
Q. Okay. But, at any rate, one way that a drug like an opioid can become significantly more used or overused is by a high level of off-label sales of that drug; correct?
MR. JAMES: Objection.
THE WITNESS: No.
BY MR. CARTMELL:
Q. So is it your testimony to this jury that high levels of off-label sales of an opioid cannot contribute to overuse of a medication like an opioid?
MR. JAMES: Objection.
THE WITNESS: Physicians make determinations of how to use those medications. And just because you have off-label use does not mean you have increased usage of the medication overall.
///

BY MR. CARTMELL:
Q. It doesn't mean absolutely, but it can; can't it?
MR. JAMES: Objection.
THE WITNESS: That's speculation I can't do.
BY MR. CARTMELL:
Q. Okay. And so -- and I understand, just so it's clear for the record, you're saying it would be speculation to say, for example, with Actiq, that if there were extremely high levels of off-label use, that that would increase significantly the amount of use of that product; is that fair?
MR. JAMES: Objection.
THE WITNESS: I -- I think -- I don't understand your question.
MR. CARTMELL: Okay. Let me try to make it more clear. I apologize. I'm not trying to be controversial here at all.
Q. The fact that Actiq had extremely high levels of off-label use -- and you're aware of that; correct?
A. Yes.
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. The fact that it had those extremely

high levels of off-label use, it's possible, is it not, that that fact made Actiq more widely used or overused than it would have been if the sales had been confined just to, for example, the cancer population; is that true?
MR. JAMES: Objection.
THE WITNESS: I can't answer that.
BY MR. CARTMELL:
Q. You don't know one way or the other; is that fair?
A. That's correct.
Q. Now, once you started, I take it one of the things that you did was look into the FDA files related to the approval of Actiq; correct?
MR. JAMES: Vague.
THE WITNESS: I don't know what documents you're referring to.
BY MR. CARTMELL:
Q. I'm just asking you in general. I would think that when you started, you needed to go into the files at Cephalon, because you were working with a new medication that you had never worked with before, and you had to go back to the file and see if you could find the FDA documents about the approval of the product; is that fair?

A. I did not look at the approval letters when I first started. I looked at the label.
Q. Okay. We're looking at pictures of the Actiq and Fentora opioid narcotics that Cephalon was manufacturing and selling during the time you were there; correct?
A. Yes.
Q. And you had responsibilities, as we've discussed, related to PR, or public relations, for those medications; correct?
A. Correct.
Q. Okay. And as we agreed before, both of these medications were approved by the FDA only for use in cancer patients who had breakthrough pain and were already opioid tolerant; correct?
A. Yes.
Q. Okay. The FDA didn't approve either of these drugs that we're looking at for use in breakthrough pain caused by back pain; correct?
A. That's correct.
Q. It didn't -- the FDA did not approve these drugs as safe and effective, either of them, for breakthrough pain associated with migraines; correct?
A. That is correct.

Q. Or headaches; correct?
A. That is correct.
Q. Or chronic pain; correct?
A. Breakthrough pain is a subset of chronic pain. So that's -- I can't -- that's not a correct characterization of the label.
Q. I understand. But there was not an indication for the use of -- or let me ask you this way: Is it your testimony that there was an indication for use of Fentora and Actiq in chronic pain?
A. Actiq --
Q. Is that your testimony?
A. Actiq and Fentora were approved -- approved for the use of breakthrough cancer pain, which is a kind of chronic pain.
Q. So you -- do you believe that your company, during the time that you were there, could promote and market Actiq for the use of chronic pain?
A. Without the presence of breakthrough pain; is that your question?
Q. I will restate it, because that's a good point.
Do you believe that Cephalon could appropriately promote or market Actiq or Fentora

during the time you were there for use in chronic pain without cancer-related breakthrough pain?
A. Not for chronic pain that was not associated with breakthrough pain.
Q. Cancer pain; right? It had to be cancer pain?
A. The label was for breakthrough cancer pain.
Q. So what I said is right; correct? It had to be cancer-related breakthrough pain; right?
A. That was not your original question. But that is correct.
Q. The FDA never found these drugs safe and effective for episodic pain; correct?
MR. JAMES: Objection.
THE WITNESS: How are you defining "episodic pain"?
BY MR. CARTMELL:
Q. Well, actually, I'm using a phrase from the documents internally from Cephalon. So how do you interpret episodic pain?
MR. JAMES: Objection.
THE WITNESS: It's -- I'm not a clinician, but it was my understanding that episodic pain was pain that was -- that would occur not on a regular

basis, but that would be of significant intensity.
BY MR. CARTMELL:
Q. Okay. And do you believe that the --
A. A kind of chronic pain.
Q. Sorry to cut you off.
Do you believe that it was appropriate for -- strike that.
Do you believe that Actiq or Fentora were indicated for the treatment of episodic pain?
A. They were approved for the use of breakthrough cancer pain.
Q. So is the answer to my question "yes" or "no"?
A. It's not my place to determine whether the prescription was appropriate. That's a physician --
Q. That's not --
A. I'm not sure I understand your question, then.
Q. Okay. I will ask it again.
Do you believe, based on your experience in the industry and based on your experience at Cephalon, that Teva -- strike that.
Do you believe, based on your experience at Cephalon and working with Actiq and Fentora, that

either of those drugs were approved by the FDA and indicated for episodic pain; "yes" or --
A. They were not approved for episodic pain.
Q. Okay. So a promotion of Fentora or Actiq for episodic pain would be an off-label promotion; correct?
A. That is correct.
Q. Now, both of these medications, when they were approved by the FDA, were approved under subpart (h) of the Act; is that correct?
MR. JAMES: Objection.
THE WITNESS: I don't recall the -- the exact segment section of the Act.
BY MR. CARTMELL:
Q. Okay. Do you recall, though, that at least both of these drugs were approved by the FDA subject to having a Risk Management Program in place?
A. That is correct.
Q. And the FDA, according to subpart (h), has the ability to require a company like Cephalon to put in place a Risk Management Program in order to sell or promote or market the approved product, if it concludes that the product is shown to be effective and it can only be safely used if

distribution or use is restricted; correct?
MR. JAMES: Objection.
THE WITNESS: Again, I don't remember the exact wording of subpart (h), as you indicated it was called.
BY MR. CARTMELL:
Q. I understand. But was your general understanding that the FDA has the power to say to drug manufacturers, like Cephalon, that if they think the drug can only be used safely and effective with a Risk Management Program, they can require the company to put a Risk Management Program in place; fair?
A. That's correct.
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. Okay. And the Risk Management Program is an agreement or commitments from the pharmaceutical company to the FDA that they will follow the commitments in the Risk Management Program to make sure that the drug is used safely by patients; correct?
MR. JAMES: Objection.
THE WITNESS: It's beyond the scope of my responsibilities to implement the Risk Management Program.

BY MR. CARTMELL:
Q. Okay. But you were involved with implementing the Risk Management Program; correct?
A. I was on the Diversion Subteam.
Q. Right. And you were also, I think, on the Fentora Risk Management Program Launch Team; correct?
A. I was on the Fentora Launch Team. I don't remember specifically being on the -- on the Risk Management Team.
Q. We will go over that later.
But let me just ask you, Ms. Beckhardt, is it true -- your understanding, I take it, is that both of these drugs, Fentora and Actiq, were approved by the FDA with Risk Management Plans in place?
A. That's correct.
Q. Okay. And the FDA told Cephalon that it could not sell these drugs unless they had a Risk Management Program in place, and they were required to follow it; correct?
MR. JAMES: Objection.
THE WITNESS: We had a risk management place -- a Risk Management Program in place.
BY MR. CARTMELL:
Q. You knew that; correct?

A. Yes.
Q. And I take it you reviewed the Risk Management Programs in place for each of these products, Actiq and Fentora; correct?
A. Yes.
Q. And I take it, part of the reason why you needed to be familiar and review those programs is because you wanted to make sure that you and the PR Department and Cephalon were complying with those programs; correct?
A. That was -- complying with the Risk Management Program was outside of the scope of my responsibility.
Q. But you were going to be making statements to people in the public about these products; right?
A. That is true.
Q. So you needed to know what each of these Risk Management Programs said about that, didn't you?
A. That's correct.
Q. And you needed to make sure that when you were making statements to the public and to the media and to doctors and to nurses, that you were in compliance with the Risk Management Programs;

correct?
MR. JAMES: Objection.
THE WITNESS: I needed to understand the Risk Management Program.
BY MR. CARTMELL:
Q. And you needed to make sure that your statements and your work was complying with it; correct?
A. I had to comply with the Risk Management Program individually, yes.
Q. And did anybody ever train you on either of these Risk Management Programs in place for Actiq or Fentora?
A. I don't recall the training. That doesn't mean it didn't happen. I just don't recall it.
Q. Okay. And did anybody ever tell you that the company needed to make sure that it complied with the commitments in these programs?
A. Yes.
MR. CARTMELL: How long have we been going?
MR. JAMES: We have been going -- my stomach is starting to growl.
MR. WOLFE: An hour five.
MR. CARTMELL: Let's take a break.

THE VIDEOGRAPHER: We are going off the record. The time is 11:58 a m.

(Lunch recess taken at 11:58 a m.)

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AFTERNOON SESSION 12:49 P.M.

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THE VIDEOGRAPHER: We are back on the record. The time is 12:49 p.m.

BY MR. CARTMELL:

Q. Ms. Beckhardt, we're back on the record after a lunch break. Are you ready to proceed?

A. Yes.

Q. Okay. We were talking about the Risk Management Programs that the FDA required Cephalon to enter into with respect to both Actiq and Fentora, the opioid narcotics Cephalon was selling before break. Do you recall that?

A. Yes.

(Exhibit No. 7 was marked.)

BY MR. CARTMELL:

Q. I've handed you what's been marked as Exhibit 7, and I want to go through that with you.

This is a copy of the Actiq Risk Management Program that was put into place August 1st, 2001; do you see that?

A. Yes.

Q. Okay. And as we discussed, Actiq was first approved in 1998, but Anesta, another

pharmaceutical company, was the company that developed the program. So originally there was a Risk Management Program from back when Anesta was the primary seller and marketer of the drug.

But my understanding is, and you correct me if I'm wrong, this -- this Risk Management Program was put into place once Cephalon purchased Anesta and the Actiq drug from Anesta; is that fair?

MR. JAMES: Objection.

THE WITNESS: I don't know if it was changed. You're suggesting it was changed. I don't know if it was changed.

There was a Risk Management Program put in place, but I don't know if it's any different than Anesta's.

BY MR. CARTMELL:

Q. And I apologize, I didn't mean to insinuate that it had been changed. I'm just saying, because you had a new owner of the actual product, Cephalon, there needed to be a commitment by Cephalon to enter into the RiskMAP; correct?

A. Yes.

Q. And this was a copy that was provided to us from the internal files of Teva of that Risk Management Program related to Actiq. And I take it

that this is a document that you became familiar with when you started the company shortly after this; correct?

MR. JAMES: Objection.

THE WITNESS: I'm sure -- I don't recall reading it, but I suspect that I did.

BY MR. CARTMELL:

Q. Right. And we discussed that. But obviously because you were involved in making statements and messaging related to the Actiq program -- or excuse me, the Actiq product, this is a Risk Management Program that, to do your job appropriately and effectively, you would need to become familiar with; fair?

A. Yes.

Q. Okay. Now, if you will go ahead and turn to the "Introduction" section that is at page 5. And I would want to go through just some of these provisions.

You see at page 5, the introduction states:

(Reading) The Actiq Risk Management Program has been designed to address three key potential risk situations: Accidental ingestion of Actiq by children; improper patient selection;

prescriptions to and usage by opioid-nontolerant patients and diversion or abuse (end of reading).
Do you see that?
A. Yes.
Q. And was your -- strike that.
It then states that:
(Reading) Anesta and Cephalon had designed and developed this comprehensive program with the primary goal of making every reasonable effort to reduce the risk of potential untoward events in the unintended populations to the extent possible (end of reading).
Do you see that?
A. Yes.
Q. And so it was your understanding that one of the reasons that the FDA required Cephalon to enter into a Risk Management Program related to Actiq was because they had certain concerns related to its safe use or the safe use of the product --
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. -- is that fair?

MR. JAMES: Objection.
THE WITNESS: Well, one of the provisions of the Risk Management Program obviously relates to abuse and diversion. But that does not suggest that the product couldn't be used safe and effectively.
BY MR. CARTMELL:
Q. Yeah, and that's not really -- I'm not trying to say that that's not true. I'm just saying, obviously, the FDA had concerns about some things with Actiq being prescribed on the open market, and one was diversion or abuse; correct?
MR. JAMES: Objection.
THE WITNESS: It's what's in the RiskMAP, the RMP.
BY MR. CARTMELL:
Q. Okay. And they wanted Cephalon to make certain commitments to do certain things to help reduce the risks of diversion and abuse; correct?
A. That's correct.
Q. And they also wanted Cephalon to do certain things to try to reduce the risk that patients who were not the intended patients for this drug could be reduced; correct?
MR. JAMES: Objection.
THE WITNESS: According to this document

and, you know, the issue for appropriate use related to labeling.
BY MR. CARTMELL:
Q. Well, actually, there's a section we will go through in a second that talks more about the -- the appropriate population. But I see what you're referring to. It talks there about labeling; correct?
A. That's correct.
Q. Okay. It states:
(Reading) A lengthy series of events must occur in sequence before a risk event can occur. And any other multiple RiskMAP elements could intervene to interrupt the sequence and prevent the risk event (end of reading).
Do you see that?
A. I don't -- okay. Thank you.
Q. And then it states:
(Reading) The purpose of the RiskMAP is to ensure the safe use of this product (end of reading).
Do you see that?
A. Yes.

MR. JAMES: RMP, not RiskMAP.
THE WITNESS: Yeah.
MR. JAMES: Just so it's --
THE WITNESS: Clear.
MR. CARTMELL: I'm sorry.
THE WITNESS: The RMP is prior to the RiskMAP, prior to the RMS.
BY MR. CARTMELL:
Q. Let me restate it. It then says:
(Reading) The purpose of the Risk Management Program is to ensure the safe use of this product (end of reading).
Right?
A. That's correct.
Q. And I take it that was your understanding, it's Cephalon's understanding, that this Risk Management Program was put into place to try to make patients who were taking Actiq safe; correct?
MR. JAMES: Objection.
THE WITNESS: It was intended to ensure that there was proper patient selection.
BY MR. CARTMELL:
Q. And -- and that's a safety issue with

patients; correct?
A. The use of Actiq or any transmucosal product in an opioid-nontolerant patient was the concern with the risk.
Q. Well, okay. Let's go through this. But if you could answer my question.
My question was: This clearly states that the purpose of this Risk Management Program was to ensure the safe use of this product; correct?
A. That's correct.
Q. And Cephalon's understanding and your understanding was that was what this program was about and the commitments by the company were about; correct?
MR. JAMES: Objection.
THE WITNESS: The commitment was made before I got there. But that's -- it's -- it is for appropriate -- it was intended to ensure appropriate use of the product.
BY MR. CARTMELL:
Q. Okay. And safe use; correct?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. It says, "the safe use"; correct?
A. It says it, yes.

Q. And then there's key messages for this Risk Management Program; you see that below?
A. Yes.
Q. And one of them is proper patient selection and prevention of diversion and abuse messages; do you see that?
A. Yes.
Q. So the FDA was asking the company to send certain messages to physicians and patients and pharmacists, and those messages included that there needed to be proper patient selection for Actiq; correct?
A. That's correct.
Q. And then it defines more clearly on the next page a section called, "Proper Patient Selection Messages." Do you see that?
A. Yes.
Q. And there's several of them. And one that you mentioned is that it needs to be an opioid-tolerant patient?
A. Correct.
Q. And then it can't be a specifically contraindicated group of patients taking this, which is opioid-nontolerant patients; correct?
A. That's correct.

MR. JAMES: Objection.
BY MR. CARTMELL:
Q. And then you can't -- they shouldn't -- strike that.
And then a proper patient is not somebody who is using Actiq for acute pain or postoperative pain; correct?
A. That's correct.
Q. Okay. And then it states -- and I want to focus on this for the jury -- it states:
(Reading) Actiq is specifically indicated solely for the treatment of breakthrough cancer pain in chronic opioid-tolerant cancer patients (end of reading).
Do you see that?
A. I see that, yes.
Q. So the company there is committing to the FDA, that's risk management, that it's going to ensure proper patient selection, which is cancer patients who have breakthrough pain and are opioid tolerant; fair?
A. That's what's --
MR. JAMES: Objection.
THE WITNESS: -- on the label.

BY MR. CARTMELL:
Q. And that was your understanding; correct?
MR. JAMES: Objection.
THE WITNESS: My understanding of what? Sorry.
BY MR. CARTMELL:
Q. Just your understanding that the company was committing that those were going to be the messages that would be given about this product; correct?
MR. JAMES: Objection.
THE WITNESS: It was the label and communications were to be consistent with the label.
BY MR. CARTMELL:
Q. Right. But my point is, specifically the commitment by the company included giving messages that Actiq is specific -- specifically indicated solely for the treatment of breakthrough cancer pain in chronic opioid-tolerant cancer patients; correct?
A. And we did communicate that, yes.
MR. CARTMELL: Object. And move to strike. And answer it again.
Q. Specifically the commitment by the

company included giving messages that Actiq is specifically indicated solely for the treatment of breakthrough cancer pain and chronic opioid-tolerant cancer patients; correct?

MR. JAMES: Objection.

THE WITNESS: It's the labeled indication.

BY MR. CARTMELL:

Q. So correct; right? I'm really not trying to be --

A. It's the labeled indication. So, yes, one is to market according to the labeled indication.

Q. That's really not -- I'm not trying -- I mean, I'm not trying to be disrespectful. That's not my question. If you could just try to answer my question, and then I will move on.

One of the commitments that the company gave in this Risk Management Program was that it would give proper patient selection messages, including a message that Actiq is specifically indicated solely for the treatment of breakthrough cancer pain in chronic, opioid-tolerant cancer patients; correct?

MR. JAMES: Objection.

THE WITNESS: That was a proper patient selection message.

BY MR. CARTMELL:

Q. Okay. And then it talks about messages related to the prevention of diversion and abuse; correct?

A. Yes.

Q. And the FC -- the F -- excuse me, the FDA indicated that one of the messages related to that would be that Actiq is a Class 2 medication; right?

A. Yes.

Q. And that the company would tell people, physicians, pharmacists, nurses, that Actiq may be habit forming; correct?

MR. JAMES: Objection.

THE WITNESS: That's one of the messages, all opioids can be habit forming.

BY MR. CARTMELL:

Q. If you turn to page 12, there's actually a section on "Professional Medical Education." And it states that:

(Reading) Cephalon will work in conjunction with the FDA and interface with licensing boards and professional associations on the development and dissemination of educational materials

related to Actiq (end of reading).

Do you see that?

A. Yes.

Q. And is it true that that was one of the things that you would do from time to time, is interface with professional associations?

A. Not in the context of professional medical education.

Q. But just in general, that was a group -- professional associations were a group that you would partner with from time to time related to sending messages on the breakthrough pain disease --

A. Correct.

Q. -- things like that?

Okay. "Key Message Points," it states:

(Reading) The education of physicians, nurses, pharmacists, caregivers, and patients on the safe use of Actiq is an integral part of the Actiq Risk Management Program (end of reading).

Do you agree with that?

A. Yes.

Q. It states that there are three main messages. And I want to focus on the last two, which are proper patient selection messages; right?

A. Yes.

Q. And remember from the prior page, that included that the proper patients would be limited solely to cancer patients who had breakthrough pain and were opioid tolerant; correct?

A. Yes.

Q. Okay. It states, "Prevention of diversion and abuse messages." Do you see that?

A. Yes.

Q. If you turn the page, it states at the top:

(Reading) These key educational messages primarily focusing on safety are provided to the physicians, nurses, and pharmacists through the communication vehicles which are discussed on the following pages (end of reading).

And so this Risk Management Program, then, had tools and vehicles that the company was committing to use to try to get these messages out to pharmacists and physicians and nurses and patients; correct?

MR. JAMES: Objection.

THE WITNESS: I was not responsible for

that, but that is -- we were -- we did give message education to physicians, nurses, and pharmacists.
BY MR. CARTMELL:
Q. My only question was, what we are about to go through, were those messages that the company -- excuse me, those tools and vehicles that the company committed to using to get out those messages; correct?
MR. JAMES: Objection.
THE WITNESS: I don't understand your question.
BY MR. CARTMELL:
Q. One -- one of those vehicles was the Actiq Speakers Bureau/Medical Education Programs; do you see that?
A. Yes.
Q. Now, that was, I don't think, an area that you were involved in working on; is that right?
A. That's correct.
Q. Okay. That would have been the Marketing Department?
A. No. It would have been -- part of it. The speakers bureau may have been part of it. But there was also the medical education programs would have been led by our Medical Department.

Q. Okay. But the speakers bureau would have been the sales reps --
A. No.
Q. -- involved with marketing?
A. No. It would have been the Marketing Department, not the Sales Department.
Q. Okay. Then I misunderstood you, because I thought you said "may have been." Let's make the record clear.
The Actiq Speakers Bureau/Medical Education Programs, those were not tactics or vehicles that you were involved with; correct?
A. That's correct.
Q. But, for example, the Actiq speakers bureau, that was something that the Marketing Department was involved with; right?
A. Correct.
Q. Okay. And then another vehicle below that is, "Publications." Do you see that?
A. Yes.
Q. And it talks here about the company is agreeing to have manuscripts selected for publications, are those that combine a specific focus into the key cancer pain management audience.
Do you see that?

A. Yes.
Q. Okay. Turn, if you will, please, to page 15. This Risk Management Program talks about the Actiq launch program and states that:
(Reading) Actiq will target a relatively small group of clinicians. The emphasis of the promotion will be highly educational (end of reading).
Do you see that?
A. Yes.
Q. And it defines more on the next page, Ms. Beckhardt, who that target audience is; right?
A. Yes.
Q. And it states:
(Reading) The target physician audience for Actiq is a group of approximately 5,000 oncologists and pain specialists, their nurses and office staff. These physicians are already using Class 2 opioids to treat cancer pain, are generally knowledgeable about breakthrough cancer pain and should understand the appropriate use of Actiq for opioid-tolerant cancer patients (end

of reading).
Do you see that?
A. Yes.
Q. And was your understanding in working with occasionally the Marketing Department -- and as a manager in the PR Department, that's the group of doctors that Cephalon committed to the FDA that it would call on?
MR. JAMES: Objection.
THE WITNESS: Our sales force called on oncologists and pain specialists.
BY MR. CARTMELL:
Q. And that's -- that was a commitment right here, defining who the doctors are that the sales force should call on; correct?
MR. JAMES: Objection.
THE WITNESS: It is -- we indicated that we would call on oncologists and pain specialists.
BY MR. CARTMELL:
Q. But this makes it clear, the company is telling the FDA -- right? -- that it's going to limit who it targets, what physicians it targets, that those that have knowledge about the treatment of cancer with opioids; correct?
MR. JAMES: Objection.

THE WITNESS: Those are the physicians that we targeted.
BY MR. CARTMELL:
Q. Okay. And that was the commitment to the FDA; correct?
MR. JAMES: Objection.
THE WITNESS: You keep using the word "commitment." And I'm not sure.
BY MR. CARTMELL:
Q. You're not willing to say that this was a commitment to the FDA?
MR. JAMES: Objection.
THE WITNESS: It was a part of the Risk Management Program, which was approved by the FDA.
BY MR. CARTMELL:
Q. The FDA required it; right?
A. Yes.
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. And they required these things to be done by your company; correct?
MR. JAMES: Objection.
THE WITNESS: Yes.
BY MR. CARTMELL:
Q. Okay. And my only point is: Right

here, this is talking about who the targeted physicians will be. And this is a commitment, is it not, from the company that it will be a small group of physicians, and only physicians that have knowledge and expertise related to treating cancer patients; correct?
A. And they were --
MR. JAMES: Objection.
THE WITNESS: -- our target audience.
BY MR. CARTMELL:
Q. You're saying that your company followed this?
A. I'm saying that oncologists and pain specialists were our target -- our primary target audience.
Q. And they needed to be, would you agree with me, pain specialists who had special expertise and knowledge about treating cancer?
MR. JAMES: Objection.
THE WITNESS: They needed to have special knowledge to treat cancer pain, not in treating cancer.
MR. CARTMELL: Okay. I'm sorry. That's a good clarification. Thank you for that.
Q. Okay. If you go to page 27, there's

a specific section related to off-label usage. Do you see that?
A. Yes.
Q. We talked about that. Off-label usage is usage of the medication for a condition that is not approved by the FDA; correct?
A. Correct.
Q. Okay. It states:
(Reading) Whenever a problem of off-label usage becomes known and individual prescribers are identified, the following activities will take place (end of reading).
And then it outlines the things that the company needs to do; correct?
A. Yes.
Q. It needs to send letters; right?
A. Yes.
Q. It needs to send letters to the Medical Department of those prescribers that they deem to be a problem; correct?
A. Needed to be sent from our Medical Department to prescribers.
Q. Okay. And then prescribing patterns of these doctors will be monitored for these

physicians who are prescribing off label; correct?
A. Correct.
Q. Okay. And then it talks about groups of prescribers below. Do you see that?
A. Yes.
Q. (Reading) If groups of physicians, such as a particular specialty, are identified as having prescribed Actiq inappropriately, and these prescriptions represent potential off-label usage greater than 15 percent of total quarterly Actiq prescriptions, Cephalon will contact the appropriate professional society -- and then, for example, the American College of Surgeons, the American Society of Anesthesiologists (end of reading).
Do you see that?
A. Yes.
Q. And I think you said earlier that those were not societies or professional societies that you worked with; is that right?
A. Not that I personally worked with.
Q. Okay. Let me ask you: Did anybody

ever ask you to contact any professional society because of off-label usage of the docs?

A. It would -- it would not have been my -- me. It would have been come from the Medical Department.

Q. In the next paragraph it says:

(Reading) Prescribing patterns will be monitored for the physician groups in question. And should the level continue to exceed 15 percent (end of reading) --

That's talking about off-label level; correct?

A. Yes.

Q. -- (Reading) 15 percent of total Actiq prescriptions for two additional quarters, an aggressive educational program will be initiated by mail, clearly warning of the potential liabilities of prescribing Actiq to inappropriate patient populations (end of reading).

Do you see that?

A. Yes.

Q. And, again, referring back to the

agreement, it states that inappropriate patient populations include those patients who don't have cancer; correct?

A. That's correct.

MR. JAMES: Objection.

THE WITNESS: That's correct. But if the first statement in -- that we read talked about the importance of a -- the primary concern of the RMP was to look at opioid-nontolerant patients, to make sure that people taking Actiq were opioid tolerant.

BY MR. CARTMELL:

Q. Okay. You've said that a couple times. Show me where in this document it says the primary concern was for the patients to be opioid tolerant.

A. I will say medically that is the primary concern because that -- it is that that causes the potential risk of respiratory depression.

Q. Okay. I just want to make it clear for the jury, though, nowhere in this agreement does it say that the primary concern is opioid intolerance; correct?

A. It may not say the word "primary"; however, in the page that you referenced, page No. 5, the Risk Management Program was designed to address

three potential risk situations, and improper patient selection, as I understand it in this document, is described as prescriptions to and usage by opioid-nontolerant patients.

Q. Okay.

A. And I understand that later the -- there is discussion about the population that the indication was for were opioid-tolerant cancer patients. I understand that. But I'm just stating that the risk that was stated here as the key three potential risk situations referred to opioid-tolerant patients.

Q. Okay. But my point is, if you turn to the next page, there are selection -- proper patient selection messages which defines what a proper patient is; correct?

A. That is correct.

Q. Okay. And it states that Actiq is specifically indicated solely for the treatment of breakthrough cancer pain; correct?

A. That's correct.

Q. Okay. It doesn't say that the primary concern is opioid intolerance or tolerance versus that; correct?

MR. JAMES: Objection.

THE WITNESS: It doesn't say it in this section, but it says it in the primary -- in the section before.

BY MR. CARTMELL:

Q. This section defines what an appropriate patient is; correct?

MR. JAMES: Objection.

THE WITNESS: This section defines what's in the label.

BY MR. CARTMELL:

Q. Right. And the label says the appropriate patient selection is cancer patients; correct?

MR. JAMES: Objection.

THE WITNESS: That is what the label -- the label states what it is indicated for.

MR. CARTMELL: Okay. Thank you.

Q. Let's move on. I want to ask you a few more questions about it.

It's clear from your viewing this document, the Risk Management Program for Actiq, that there were concerns by the FDA about abuse, misuse, diversion, and addiction related to Actiq; correct?

MR. JAMES: Objection.

THE WITNESS: There are risks because of a

C2 opioid.
MR. CARTMELL: I'm going to object and move to strike that. That's not my question.
Q. It's apparent from reviewing this document, this Risk Management Program, that the FDA required of Cephalon -- that the FDA was concerned about the risks of abuse or misuse and diversion and addiction related to Actiq; correct?
MR. JAMES: Objection.
THE WITNESS: Yes, they were concerned. But the reason they were concerned was because it was a C2 opioid.
BY MR. CARTMELL:
Q. Okay. And it's true, from looking at this document, that the FDA was requiring Cephalon, your company, to make sure that it was sending the appropriate messages to doctors, physicians, and pharmacists about the safety of this product; correct?
MR. JAMES: Objection.
THE WITNESS: Yes. And we did.
BY MR. CARTMELL:
Q. And it's true, is it not, from this Risk Management Program, that the FDA required -- that one of those messages that was required of

Cephalon to be sent to these physicians, patients, and pharmacists was that Actiq should be used solely by cancer patients with breakthrough pain and who are opioid tolerant; correct?
MR. JAMES: Objection.
THE WITNESS: Those are the messages that were required and that were given.
BY MR. CARTMELL:
Q. Okay. We will talk about whether or not they were given. Okay?
Now, is it true that you were involved in some of these vehicles that this Risk Management Program is talking about, as far as delivering messages?
A. I was not responsible for delivering messages directly to health-care providers who were prescribers or dispensing of the medication.
Q. What about delivering --
A. In that context.
Q. I'm sorry.
What about delivering messages to patient groups or industry groups or professional societies, were you involved in --
A. Yes.
Q. -- delivering those messages?

You were; correct?
A. I was involved in giving those messages as they related to management of breakthrough cancer pain and breakthrough pain.
Q. And would you agree with me that it was Cephalon's obligation to provide information through the groups that were listed that was consistent with the goals of the Risk Management Program?
MR. JAMES: Objection.
THE WITNESS: What groups -- to which -- what groups are you referring to? What section are you --
BY MR. CARTMELL:
Q. You will recall that the Risk Management Program we just went through talked about giving messages to physicians and pharmacists and patients; correct?
A. Yes.
Q. And in certain circumstances giving these messages to professional societies, for example; correct?
A. In certain circumstances, yes.
Q. And would you agree with me that it was Cephalon's obligation to provide those messages

to those groups that were consistent with the goals of the Risk Management Program?
MR. JAMES: Objection.
THE WITNESS: Yes.
(Exhibit No. 8 was marked.)
MR. CARTMELL: I'm handing you what's been marked as Exhibit 8.
Q. Ms. Beckhardt, we just looked at the Risk Management Program for Actiq. And I will represent to you that this is the Risk Management Program, sometimes referred to as the RiskMAP, for Cephalon's other opioid narcotic, Fentora.
Do you see that?
A. Yes.
Q. And, again, I take it that this is another Risk Management Program that you became familiar with during your time working at Cephalon; is that fair?
A. Yes.
Q. And you needed to become familiar with the Risk Management Program because of your involvement with providing messages related to Fentora; correct?
A. Messages related to the approval of the product and its usage and data related to it to

the media. When I worked with patient advocacy groups, my focus was on the disease state, not on the product.

Q. I understand, but -- and my point is really just that this was a document that you had to make sure that you knew well and were acquainted with, so that you could make sure when you were giving messages about Fentora, that you were complying with this agreement; correct?

A. Yes.

Q. And I want to go through this and talk a little bit about this. But if you go to page 3 of the Risk Management Program, which is the last three Bates -347. There's a section --

A. Yes.

Q. -- called, "Background."

A. Yes.

Q. And this gives the rationale for the Risk Management Program or for the RiskMAP; right?

A. Yes.

Q. And so it's clear, these are documents -- the last Actiq Risk Management Program and this, these are documents that are created actually by Cephalon; right?

MR. JAMES: Calls for -- objection.

THE WITNESS: They are created by the -- they were created by the company with the approval of the agency.

BY MR. CARTMELL:

Q. Right. So the FDA says you need to put together a program that's going to help manage risk related to these opioid products, and the company puts the document together, and then the FDA ultimately approves it; correct?

MR. JAMES: Objection.

THE WITNESS: That's my understanding.

BY MR. CARTMELL:

Q. Okay. And if you go about halfway down or three-quarters of the way down on this paragraph, it states:

(Reading) Opioid drug products have important benefits in alleviating pain but are associated with significant risks of diversion, abuse, and addiction (end of reading).

Do you see that?

A. Yes.

Q. Okay. And, again, we saw in the Actiq Risk Management Program, now with the Fentora product, the FDA is expressing its concerns related

to the risks of diversion, abuse, and addiction; correct?

A. There's risk of abuse and diversion with any C2 medications.

MR. CARTMELL: I'm going to object and move to strike that answer as nonresponsive.

Q. I will ask the question again: And, again, we saw in the Actiq Risk Management Program -- as we saw in the Actiq Risk Management Program, we now see with the Fentora product and its Risk Management Program that the FDA is again expressing its concerns related to the risks of diversion, abuse, and addiction; correct?

MR. JAMES: Objection.

THE WITNESS: Of Fentora, yes.

BY MR. CARTMELL:

Q. Okay. And it then states:

(Reading) To minimize the risks of misuse, abuse, and addiction, and diversion of Fentora, and to maximize appropriate use only in opioid-tolerant cancer patients, Cephalon has developed the secure solutions through education, communication, and understanding risks

minimization excellence program (end of reading).

Do you see that?

A. Yes.

Q. Once again, now with Fentora, just like with Actiq, Cephalon is making it clear, and the FDA has approved, that this drug needs to be appropriately used and will be appropriately used only if it's used -- strike that. Start over.

Once again, the FDA is making it clear that the appropriate use -- and Cephalon is agreeing to this -- the appropriate use is for use only in opioid-tolerant cancer patients; correct?

MR. JAMES: Objection.

THE WITNESS: Yes.

BY MR. CARTMELL:

Q. And then there's actually a statement of what the risks are. And the first risk stated is the use of Fentora by opioid nontolerant individuals; do you see that?

A. Yes.

Q. And then it talks about, as in the case with the use of all opioids, individuals using Fentora who are not tolerant to opioids are at risk for clinically significant and life-threatening

adverse events, such as respiratory depression; right?
A. That's what I indicated previously, yes.
Q. And you agree with that?
A. Yes.
Q. Okay. And we talked about you were getting diversion reports, and some of those reports actually talked about that as well; correct?
A. We get a minimum number of diversion reports. And I don't recall specific references to respiratory depression in those patients. I just don't recall.
Q. Okay. Then there's risk 2, which is, "Misuse, Abuse, and Diversion of Fentora"; correct?
A. Yes.
Q. (Reading) Opioid misuse and abuse have been known to be a precursor to addiction. The actual rate of addiction to opioids is not known, but has been estimated to be between 4 and 10 percent (end of reading).
Do you see that?
A. Yes.
Q. That's a -- that's a big percentage;

isn't it?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. As high as one out of every ten patients who take opioids?
MR. JAMES: Objection.
THE WITNESS: I can't make a judgment as to whether that's a big number or not.
BY MR. CARTMELL:
Q. Okay. "Fentanyl -- it then says below:
(Reading) Fentanyl is a known drug of abuse. And the Fentora dosage form buccal tablets has the potential to be abused (end of reading).
Do you agree with that?
A. Yes.
Q. And then Risk 3, as it's stated above on the next page is, "Unintended, Accidental Exposure to Fentora." Do you see that?
A. Yes.
Q. And then if you move forward, there are goals and objectives of this Risk Management Program, I want to talk to you about those on, page 9.

(Reading) Cephalon has identified three goals for the secure program. These goals are expressed as ideal outcomes of the Fentora RiskMAP. Associated with each of these goals there are specific and measurable program objectives that are described below. Goal No. 1: Fentora should be used only by opioid-tolerant patients with cancer (end of reading).
Do you see that?
A. Yes.
Q. Once again, this is the FDA, as it had -- strike that.
Once again, this is Cephalon in the Risk Management Program, as it did in the Actiq Risk Management Program, stating that the opioid, the fentanyl-based opioid, should only be used with patients that have cancer; correct?
MR. JAMES: Objection.
THE WITNESS: That was an objective of the RiskMAP.
BY MR. CARTMELL:
Q. And it states, goal No. 1 below:
(Reading) Fentora should be used only

by opioid-tolerant patients with cancer (end of reading).
And then it gives some objectives that the company is committing to do to ensure that that is -- is the case; correct?
A. Correct.
Q. One is to educate physicians that Fentora should not be used in opioid-nontolerant patients; correct?
A. Yes.
Q. That's one. But if you look at No. 3, the company is also committing to educate pharmacists and other health-care personnel of the importance of Fentora being prescribed, distributed and used only by opioid-tolerant patients with cancer. Do you see that?
A. Yes.
Q. So, again, Cephalon is telling the FDA and committing to the FDA that it's going to educate these health-care providers and tell them that these products should only be used by patients with cancer; correct?
A. It was an objective to educate those health-care professionals on the indication of the medicine.

Q. Right. And that's a prudent thing for the company to do, because otherwise they would be off-label promoting?
MR. JAMES: Objection.
THE WITNESS: That's correct.
BY MR. CARTMELL:
Q. It then, on the next page, talks about the overall strategy. And it states:
(Reading) In developing the goals, objectives and tools for a secure program, Cephalon relied on its experience with implementing its Risk Management Program for Actiq (end of reading).
Do you see that?
A. Yes.
Q. Now, were you involved in developing this Risk Management Program?
A. For Fentora?
Q. Yes, ma'am.
A. I was -- I was not involved in its final form. I was involved in a committee that was involved in writing sections of it in terms of what other people decided that should be, you know, the -- putting things, what other people, said to paper,

drafting it --
Q. I see.
A. -- in certain sections. Not all sections, but certain sections.
Q. Okay. And then after this was approved by the FDA, did you believe yourself that you needed to comply with this Risk Management Program for Fentora?
A. Yes.
Q. Okay. If you go to page 15, there are sections related to the strategy and tools associated with these goals.
A. Yes.
Q. And it states, "Strategy and tools associated with goal No. 1." And goal No. 1 is that Fentora should be used only by opioid-tolerant patients with cancer. It states:
(Reading) A variety of tools will be used to communicate and reinforce the message that Fentora should be used only by opioid-tolerant patients with cancer. The tools have been designed for specific purposes to be used as part of an organized communications campaign intended to influence

prescribers, pharmacists, and patients (end of reading).
Do you see that?
A. Yes.
Q. And that is, in other words, Cephalon committing to use an educational program to influence physicians, pharmacists, and patients that the only patients that should use this drug have cancer; correct?
MR. JAMES: Objection.
THE WITNESS: That's what it states.
BY MR. CARTMELL:
Q. The next paragraph states:
(Reading) From the outset, health-care professionals will be alerted to the risks of this new product through product labeling and promotion. They will be educated about the product's improved indication as well as about the definition of opioid tolerant (end of reading).
Correct?
A. Correct.
Q. The next paragraph talks about "letters, visits, and assessments by field

representatives. A Fentora website and targeted education and outreach programs directed to pain centers of excellence and professional societies."
Do you see that?
A. Yes.
Q. And that's saying that all of these things will be used, these vehicles -- letters, visits to doctors' offices, websites, targeted education programs -- to specifically tell these health-care providers that Fentora should only be used by cancer patients who have breakthrough pain; correct?
MR. JAMES: Objection.
THE WITNESS: To my knowledge, these -- that is what it says. And that's what was -- those things were done.
BY MR. CARTMELL:
Q. And then if you go to page -- I apologize. I apologize, but I skipped forward too far. I want to go back to page 12 and direct your attention to the third paragraph down in the middle. It talks about some of the education and vehicles that the company is committing to do and utilize. It states:
(Reading) Using academic centers,

professional societies and pain centers of excellence -- pain centers identified by Cephalon as having excellent faculties and resources. Additional education will be provided through training and independent continuing medical education. Note: CME programs will be conducted in accordance with FDA and ACCME guidelines (end of reading).

Were you involved actually in planning or helping to plan continuing medical education programs related to Fentora or Actiq?

A. No.

Q. (Reading) The importance of interpersonal communication is based not only on the need to provide education to prescribers but also to motivate behavorial adherence with the screening process to assure only appropriate patients are prescribed Fentora (end of reading).

Do you see that?

A. I see that.

Q. And do you agree with that?

A. It is -- it is important to convey what the label is.

Q. Right. And then the last sentence: (Reading) Because physicians in various localities may prefer to learn via different methods, Cephalon will work with pain centers of excellence to provide teaching opportunities consistent with the needs and resources identified by each center (end of reading).

Were you involved in that at all?

A. No.

Q. If you go to page 59, there's an appendix that indicates the tools that Cephalon is to employ and specifically related to physician education targeted to members of professional societies. It says: (Reading) Professional societies will be contacted to offer educational opportunities to learn about Fentora and key messages and risks described in the RiskMAP, including the risk for misuse, abuse, and diversion. The educational platform for these

offerings will be -- include symposia at the professional societies' meetings and teleconferences with interested members (end of reading).

Do you see that?

A. Yes.

Q. Were you involved with that?

A. No.

Q. So that was not something that fell within your purview?

A. That's correct.

Q. Okay. Now, again, having gone through now the Fentora Risk Management Program, would you agree with me that Cephalon had entered into an agreement, a Risk Management Program, and committed to a Risk Management Program that was designed to ensure, to the best of its ability, the safe use of Fentora?

MR. JAMES: Objection.

THE WITNESS: That was the intent of the Risk Management Program and the RiskMAP.

BY MR. CARTMELL:

Q. And it was designed in part to relieve concerns that the FDA had, and I'm sure Cephalon had, about abuse and misuse and diversion

and addiction related to Fentora, like any opioid; correct?

A. Like any opioid.

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. And the primary way that Cephalon was going to make sure that this product Fentora was used by the appropriate patients, meaning those patients who had cancer and breakthrough pain, was through the tools, educations, letters, meetings with professional societies, and sending those messages in a redundant manner to make sure they understood; correct?

MR. JAMES: Objection.

THE WITNESS: I'm not sure I understand your question.

BY MR. CARTMELL:

Q. The Fentora Risk Management Program makes it clear that Cephalon is committing to use various tools, including letters, performing education programs, meeting with professional societies, those types of things to ensure that they know that Actiq -- excuse me, that Fentora and the appropriate patients for the use of Fentora were cancer patients with breakthrough pain; correct?

MR. JAMES: Objection.
THE WITNESS: Correct.
(Exhibit No. 9 was marked.)
BY MR. CARTMELL:
Q. I'm going to hand you what has been marked as Exhibit 9. And I just want to ask you a quick question -- I'm not going to ask you in detail about this right now. But I want to ask you a quick question about the first page of the memorandum, if you turn the cover, which is a memorandum dated April 26, 2008. Do you see that?
A. Yes.
Q. And first let me ask you this: You were aware Cephalon at some point had asked the FDA if the indication for Fentora could be broadened to include treatment of not just cancer pain but other types of chronic pain; correct?
A. Yes. After conducting three randomized placebo-controlled clinical trials.
Q. Okay. And I think that happened in something like 2006 or '07; is that right?
A. I don't recall the exact dates. But that sounds approximately right.
Q. Okay. And, as you said, the company Cephalon at that time submitted, I think you said,

there were placebo-controlled trials; correct?
A. That's correct.
Q. To the FDA; right?
A. That's correct.
Q. And the FDA ultimately -- and we will talk about this later -- said that although it believed that Fentora might be efficacious for treatment of other pain conditions, like back pain and other chronic pain conditions, it did not believe that Fentora could be used necessarily safely with respect to abuse and misuse and diversion; correct?
MR. JAMES: Objection.
THE WITNESS: I don't remember the exact language that the FDA used.
BY MR. CARTMELL:
Q. At any rate, you recall, I suspect, that the FDA denied Cephalon's request to expand the indication; correct?
A. That is correct.
Q. Okay. This is a memo from the Director of the Division of Anesthesia and Analgesia & Rheumatology Projects, Bob Rappaport; do you see that?
A. Yes.
Q. And this has to do with the company's

request to expand the indication beyond cancer pain. And I want to focus your attention on the first paragraph. It states:
(Reading) Fentora was approved in 2006 for the treatment of breakthrough pain in patients with cancer who already treated with around-the-clock opioids. Actiq, approved for the same indication in 1998, was the first oral transmucal fentanyl product developed for this indication." Do you see that.
A. Yes.
Q. That's just a little bit of history that we talked about. Actiq came first, and it was only for cancer pain, breakthrough cancer pain; Fentora came second, and it was only for breakthrough cancer pain; correct?
A. Correct.
Q. Then it says, "Actiq is a lozenge that is presented on a stick making it easily removable from the mouth, while Fentora is a lozenge without a stick." It as a tablet; right?
A. That's correct.
Q. "Because approval of these products

represented availability of fentanyl without the necessity of intravenous access, FDA had numerous discussions with the sponsors during the development of the products to address our concerns regarding the potential for abuse and misuse, and the potential for accidental exposure to these formulations."
Do you see that?
A. I see that.
Q. And when it refers to numerous discussions with the sponsors, the sponsor is Cephalon; correct?
A. That's correct.
Q. For Fentora?
A. And the Risk Management Program and the risk maps were intended to address those very concerns.
Q. Right. And it states, "In order to prevent abuse and misuse, an accidental exposure to Actiq and Fentora, particularly by children, rigorous Risk Management Programs were included as part of the approval of the products"; right?
A. That's correct.
Q. We just went through those programs, didn't we?
A. That's right.

Q. "These Risk Management Programs were designed to limit the prescribing of these products to opioid-tolerant patients with breakthrough pain from cancer with the intent that this would limit the overall prescribing of the medication and perhaps limit the amount of diversion for abuse and the number of accidental exposures."

Do you see that?

A. I see that.

Q. In one sentence the FDA used three times the word "limit." Do you see that?

A. I do see that.

Q. And what the FDA is expressing there is that when it put these Risk Management Programs in place to govern the use of Actiq and Fentora, it was trying to make sure that there was limited use of the products only to cancer patients; correct?

A. We had --

MR. JAMES: Objection.

THE WITNESS: We had 0.2 percent of the marketplace. Our product was in a very different place than other opioid products.

MR. CARTMELL: I'm going to object and move to strike that. And ask the question again. That's -- that's not responsive to this question.

And we will talk about that. But let me ask the question again.

Q. And what the FDA is expressing there is that when it put these Risk Management Programs in place to govern the use of Actiq and Fentora, it was trying to make sure that there was limited use of these products only to cancer patients; correct?

MR. JAMES: Objection.

THE WITNESS: That's what it states here.

BY MR. CARTMELL:

Q. All right. We will come back to this document later, but I want to move on.

MR. JAMES: If you're at a breakpoint, I think we've been going an hour.

MR. CARTMELL: Okay.

MR. JAMES: Take a quick break.

THE VIDEOGRAPHER: We are going off the record. The time is 1:44 p m.

(Recess taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 1:57 p m.

BY MR. CARTMELL:

Q. Ms. Beckhardt, we're back on the record after a short break. Are you ready to proceed?

A. Yes.

Q. We're talking about Exhibit 9, which is the FDA's memo from the Director, Bob Rappaport. And specifically we're talking about this highlighted sentence where it states that:

(Reading) the Risk Management Plans were designed to limit the prescribing of these products, with the intent that this would limit the overall prescribing of the medication (end of reading).

Would you agree with me that that is talking about limiting the prescribing to cancer patients?

A. That's what it states, yes.

Q. And then it's talking about, by limiting this prescribing to cancer patients, it had the intent that this would then limit the overall prescriptions of the medication; right?

MR. JAMES: Objection.

THE WITNESS: That's what it states here.

BY MR. CARTMELL:

Q. And you will recall, we looked at that email from your contemporary Terrence Terifay, remember that?

A. Yes.

Q. Where he stated that the bottom line is, as we all know, greater availability of a drug directly correlates to the abuse and diversion. And we agreed that that makes sense; correct?

A. Yes.

Q. And so what the FDA is stating here is that they have that same concern, that they wanted this drug -- or these drugs, Actiq and Fentora, to be limited to cancer patients because their concern was if it wasn't limited, it would be more available. And then it says specifically that could lead to more abuse and misuse and diversion; correct?

MR. JAMES: Objection.

THE WITNESS: It states that perhaps it could limit.

BY MR. CARTMELL:

Q. And you agree with that; correct?

A. With that qualifier, yes.

Q. Okay. All right. Now, it's pretty clear that the FDA wanted Cephalon to keep pretty tight reins on these drugs; correct?

MR. JAMES: Objection.

THE WITNESS: I think that's not a question for me. That's a question for FDA, what their intent was. It's clear that the risk -- we had Risk

Management Programs.
BY MR. CARTMELL:
Q. Okay. And all I'm really getting at is what we just looked at it. It gave the history of Actiq, it gave the history for Fentora, and then it said for both of them we had Risk Management Programs that were intended to limit the number of prescriptions to those people that only had cancer; right?
MR. JAMES: Objection.
THE WITNESS: To limit the prescribing to people with cancer.
BY MR. CARTMELL:
Q. Right. And so would you agree with me, based on those Risk Management Programs, that Cephalon had committed to the FDA that it was going to try to ensure that that was the case?
MR. JAMES: Objection.
THE WITNESS: That's what these documents state.
BY MR. CARTMELL:
Q. Okay. Now, but it's true, is it not --
Are you okay? You have got water?
MS. HUDNALL: Yes.

BY MR. CARTMELL:
Q. Ms. Beckhardt, the truth is that even though the FDA wanted to restrict and limit the use of Actiq and Fentora, Cephalon wanted the opposite; isn't that true?
MR. JAMES: Objection.
THE WITNESS: I -- I -- I don't believe that that's a fair characterization.
BY MR. CARTMELL:
Q. It's true that Cephalon wanted the opposite of what it told the FDA; it wanted to maximize the use of these drugs, the prescriptions of these drugs in all kinds of patient conditions, correct?
A. No.
MR. JAMES: Objection.
THE WITNESS: That's not correct.
BY MR. CARTMELL:
Q. It's true that Cephalon wanted to maximize these drugs for use in all kinds of pain conditions because it wanted to maximize profits; correct?
MR. JAMES: Objection.
THE WITNESS: That's not true.
(Exhibit No. 10 was marked.)

BY MR. CARTMELL:
Q. I'm going to hand you what has been marked as Exhibit 10. As you can see, Ms. Beckhardt, Exhibit 10 is a Fentora strategic marketing plan from 2007; do you see that?
A. Yes.
Q. And this was produced from the files, internal files at Teva. And I'd like to ask you a few questions about this. But this -- strike that.
This PowerPoint starts out with -- or includes a -- what's called a -- I'm sorry. I'm in the wrong place. Let me start over.
Ms. Beckhardt, this PowerPoint, Fentora presentation from 2007, has a market analysis included in it at page 13 and several pages before that. Do you see that?
A. Yes.
Q. This is a market analysis, and it states, "Overall Market Attractiveness," at the top. Do you see that?
A. Yes.
Q. And for the jury's sake, when you're talking about a market, what are you talking about?
MR. JAMES: Objection.
THE WITNESS: Market is the -- the universe

of -- of potential prescribers. But the universe does not necessarily include the prescribers that you would market to.
BY MR. CARTMELL:
Q. Right. So -- and it's -- it's actually -- I think you meant to say this, but the market is the universe of patients actually that could be prescribed the drug; correct?
A. This is not a product that you market to -- direct to patients. The actual market are the prescribers.
Q. Okay. But when you -- when you look at this analysis, for instance, this has a chart, as you can see, that includes the number of patients --
A. Right.
Q. -- right? And the conditions across the bottom of it that exist in the potential market; right?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. Do you see that?
A. It says it -- that exists within the context of the chronic pain market.
Q. Okay. So let's talk about this -- this page of this PowerPoint in 2007. It states:

(Reading) Chronic pain market has significant potential due to high prevalence (end of reading).

Do you see that?

A. Yes, I see that.

Q. Okay. And "significant potential due to high prevalence." This is saying that the market for all chronic pain -- significant potential means a lot of potential for prescriptions; right?

MR. JAMES: Objection.

THE WITNESS: These were not -- the implication of this has nothing to do with prescriptions for chronic pain. This is a -- this is a market analysis of potential patients who have breakthrough pain, not which is, as I mentioned before, a kind of chronic pain. But the intent was never to treat just chronic pain.

BY MR. CARTMELL:

Q. Okay. I understand that. Let me see if I understand this analysis, Ms. Beckhardt, and see if you can explain this to the jury.

It says:

(Reading) Chronic pain market has significant potential due to high prevalence (end of reading).

What does that mean?

MR. JAMES: Objection.

THE WITNESS: What this chart is showing are the proportion of people with different conditions who are treated with opioids already around the clock.

BY MR. CARTMELL:

Q. Okay. And so this includes the whole market, if you included all chronic pain conditions; is that right?

A. No.

Q. Okay. This includes just some of those conditions; correct?

MR. JAMES: Objection.

THE WITNESS: Yes.

BY MR. CARTMELL:

Q. And what is the condition on this chart that Fentora is indicated for?

A. Cancer pain.

Q. Okay. So if we look at the left side of this chart, that's being -- it's got a square around it right now -- that is the group of patients that Fentora was indicated for; correct?

MR. JAMES: Objection.

THE WITNESS: According to the approved

indication, yes.

BY MR. CARTMELL:

Q. Okay. And it looks like, if you look at prevalence, that means -- prevalence is the number of patients; right?

A. Yes.

Q. And that's like -- it doesn't look like it's even --

A. It's not -- prevalence is the -- if I recall the definition -- is the number of new patients.

Q. Okay. So the cancer number of new patients at this time, according to this chart, it looks like is about half of two million people; is that right?

A. I -- I suppose. I can't -- I can't read it clearly.

Q. Okay. And then there's these other conditions that Fentora is not indicated for; correct?

A. That's correct.

Q. In other words, the FDA has not said that it's safe and effective for the use of back pain or arthritic pain or neuropathic pain or headache; correct?

A. That's correct. But these are all patients who are treated with opioids around the clock, a substantial portion of them.

Q. Right. But they're -- they're not treated with fentanyl-based opioids that are only approved for breakthrough pain in cancer patients; correct?

MR. JAMES: Objection.

THE WITNESS: I -- there are some of those patients who very well may have been prescribed breakthrough pain medications, because the -- because it was an appropriate medical prescription because they were -- at the doctor's discretion, not the company's discretion, because those patients were opioid tolerant.

BY MR. CARTMELL:

Q. Okay. So if you look at, for example, back pain. The prevalence of back pain patients, who are potentially treated with -- or strike that.

The prevalence of back pain patients, it looks like, is more like nine million patients; correct?

A. Not the -- it's the -- that would be number of patients, not prevalence, but the number of

patients -- I'm not sure if it's prevalence or incidence -- who were treated with opioids around the clock, yes.

Q. Okay. And then if you look at arthritis pain, the number of patients -- and I think it is prevalence on the left because it's the red color -- is more like, you know, 11 million patients; correct?

A. Oh, the prevalence. Okay.

Q. Neuropathic pain is almost ten million patients; right?

A. Yes.

Q. Headache is over ten million patients; isn't it?

A. Yes.

Q. So the number of cancer pain patients is way, way less than the number of back pain patients or arthritis pain patients or neuropathic pain patients or headache pain patients; right?

MR. JAMES: Objection.

THE WITNESS: Because there's -- there are fewer cases, thank goodness, of cancer than some of these other more common conditions.

BY MR. CARTMELL:

Q. Right. So if the company was going

to just limit its prescriptions or if it was going to only limit -- strike that.

So if Fentora was limited to only use in cancer pain patients, the number of prescriptions would be much, much less than if it expanded into, for, say -- for example, back pain; correct?

A. I can't say that.

Q. What about if you expand it into arthritis pain?

A. I can't say that because I don't know what the -- I do not recall what the proportions of cancer pain -- how -- how far into the market we got. I just don't recall.

Q. When this slide says, "Chronic pain market has significant potential due to high prevalence," this is talking about the entire group of cancer pain, back pain, arthritis pain, neuropathic pain, and headache pain; correct?

A. That's correct.

Q. And when it's talking about the entire group, all of those, other than cancer pain, would be prescriptions for Fentora that would be off label; correct?

A. This does not suggest that that it's prescriptions for Fentora.

Q. Let me back up. And I will move to strike that and ask it again.

And when it's talking about the entire group, all those other groups, other than cancer pain listed here, would be prescriptions for Fentora that would be off label; correct?

MR. JAMES: Objection.

THE WITNESS: This does not talk about prescription. It talks about the number of people who are treated with opioids within a particular community of patients. It does not say anything about numbers of prescriptions.

BY MR. CARTMELL:

Q. This is talking about what is our potential market to sell Fentora to; correct?

A. Yes.

Q. Okay.

A. But that's not the question you asked me.

Q. Let's get down to what this is talking about.

Ms. Beckhardt, this chart is talking about what is the potential market to possibly sell Fentora to; correct?

A. That's correct.

Q. And it's not just including cancer pain, but it's including back pain, arthritis pain, neuropathic pain, and headache pain; correct?

A. They are indicating that that's part of the marketplace, yes.

Q. Right. But everything other than cancer pain on this, if in fact these people were prescribed -- and I know it's a doctor's decision -- Fentora, those would be off-label usage; correct?

A. That's correct.

Q. Okay. And if, in fact, the company was able to prescribe to all of these off-label indications on there -- back pain, arthritis pain, neuropathic pain, headache pain -- it's possible, is it not, that as it says here, the chronic pain market would have significant potential; correct?

MR. JAMES: Objection.

THE WITNESS: The -- the market that was being looked at was the market of people who were already treated with opioids. And, yes, that would have expanded the market. But it's not expanding it to the extent of the prevalence of these conditions.

It's -- they were looking at this red, not the orange square, in terms of people who are already opioid tolerant.

BY MR. CARTMELL:
Q. I understand what you're saying. So let's make that clear for the jury.
What this is looking at is really how big the market would be if you just considered the individuals in each of these conditions who was already being treated with opioids; correct?
A. That's correct.
Q. And so that's the red -- the red on the right side of each of these; correct?
A. Correct.
Q. Okay. And right now, if you just limited it to cancer pain, it would be what's being circled for the jury right now on the right side, of cancer pain; correct?
A. Yes.
Q. But what this is talking about, if you expanded the usage into back pain, arthritis pain, neuropathic pain, and headache pain, you could increase the usage potentially that much; correct?
MR. JAMES: Objection.
THE WITNESS: You could potentially increase the usage in opioid-tolerant patients if a doctor decided it was the appropriate prescription.
///

BY MR. CARTMELL:
Q. Right. And we've circled how much -- what you're saying is how much potentially the market would grow if you expanded the usage of Fentora into those other indications; correct?
A. I think the critical word there is potential.
Q. Right.
A. Because that did not happen.
Q. And so what this is talking about when it says that there's significant potential, is what we have circled here in the "Other Conditions"? That's the significant potential growth, is under each of those? The ones that are treated with around-the-clock opioids, we could add prescriptions potentially that much; correct?
MR. JAMES: Objection.
THE WITNESS: Potentially, yes.
BY MR. CARTMELL:
Q. And adding prescriptions potentially that much, by thousands and thousands of people, if that happened, that increases profits; correct?
MR. JAMES: Objection.
THE WITNESS: If you sell more product, any product, you're going to increase profit. It doesn't

matter whether it's a medicine or a box of tissues.
BY MR. CARTMELL:
Q. More sales goes to the bottom line?
A. More sales goes to the bottom line, yes.
Q. And that was something that Cephalon was interested in, was more prescriptions in other indications outside of cancer; correct?
MR. JAMES: Objection.
THE WITNESS: I can't -- I can't speak to that. I was not in the Marketing Department. So I am aware there was usage, but I'm not -- I can't say that that was the intent of the company.
BY MR. CARTMELL:
Q. Well, you, in fact, have said, have you not, that if you expanded the usage outside of just cancer, that would increase the market dramatically; correct?
MR. JAMES: Objection.
THE WITNESS: It would increase the market, yes.
(Exhibit No. 11 was marked.)
BY MR. CARTMELL:
Q. Let me hand you what's marked Exhibit 11. Exhibit 11 is an article in something

called TheStreet. Do you see that?
A. Yes.
Q. What's "TheStreet"?
A. It's a journal that is primarily intended for the investor community.
Q. Right. This is like talking about stocks and bonds; it's one of those types of journals, correct?
A. Yes.
Q. And investment in companies, and that sort of thing; correct?
A. That's correct.
Q. And this title of this article is, "Cephalon eyes new Fentora use: The company hopes the cancer pain drug can be used for broader indications."
Do you see that?
A. Yes. And this is when we were doing clinical trials, and it was before the FDA decision, to the best of my memory.
MR. CARTMELL: Object and move to strike everything after "yes." I will ask it one more time.
Q. And this title -- strike that.
Okay. And the title of this article is, "Cephalon eyes new Fentora use. The company hopes

the cancer pain drug can be used for broader indications." Do you see that?
A. Yes.
Q. Okay. It states, "Cephalon," and then is that the stock symbol next to it, "CEPH"?
A. Yes.
Q. And that's because this is something that's in an investment type --
A. Correct.
Q. -- of journal? It's talking to investors, things like that?
A. It's more like a magazine, yes.
Q. (Reading) Cephalon reported encouraging reports from a clinical trial designed to determine if the cancer pain drug Fentora could be used for broader indications. As a result, the Frazer, Pennsylvania based drug maker expects to seek regulatory approval during a third quarter for Fentora to treat jolts of intense discomfort, referred to as breakthrough pain, in people with chronic nerve pain (end of reading).
Do you see that?

A. Yes.
Q. Now, this is in January of 2007; correct?
A. Yes.
Q. At this time, in January of 2007, the FDA had only approved Fentora for use in cancer pain, breakthrough cancer pain; correct?
A. Yes. But clinical trials were underway, were completed.
Q. But my question is not that. But my question is: At this time, in January of 2007, is it not true that the only indication for this drug Fentora was for breakthrough cancer pain; correct?
A. That is correct. But this particular article is referring to results from a clinical trial.
Q. I understand that. My point is simply, there is no indication at this time for your drug Fentora to be used in anything other than cancer; correct?
MR. JAMES: Objection.
THE WITNESS: That's the indication.
BY MR. CARTMELL:
Q. Right. And the FDA had never said it was safe and effective to use Fentora for anything

other than breakthrough cancer pain as of this time in January of 2007; correct?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. Is that correct?
A. It is correct. But this is based on clinical trial results, not FDA statements.
MR. CARTMELL: Okay. I will object and move to strike everything after, "It is correct."
Q. It then states that:
(Reading) The Food and Drug Administration approved Fentora for treating breakthrough pain which the company says can last from 3 minutes to 60 minutes in cancer patients who are taking and can tolerate strong narcotic painkillers (end of reading).
And then it talks about how Fentora carries a black box warning, the FDA's strongest safety alert, about the potential for abuse.
Do you see that?
A. Yes.
Q. (Reading) The drug contains the narcotic fentanyl and it has the same abuse warning as methadone and

morphine (end of reading).
Right?
A. Yes.
Q. And then you were quoted specifically, and you say:
(Reading) The market potential for treatments other than for cancer pain is, quote, quite large (end of reading).
Do you see that?
MR. JAMES: Objection.
THE WITNESS: Yes, I see that.
BY MR. CARTMELL:
Q. And when you're talking about the market potential being quite large, you're talking about a bigger market for indications other than cancer? It's a quite large market; right?
MR. JAMES: Objection.
THE WITNESS: The market, as -- if you continue this quote, it indicates two to three million people.
BY MR. CARTMELL:
Q. Okay. So -- and we will get to that. When you say "it's quite large," the market, you're talking about the potential for treatment other than

cancer pain; correct?
A. Correct. In the context of the clinical trials.
Q. Okay.
A. That were being conducted.
Q. Well, this is in the context of January 8th, 2007, when the FDA had not said that your drug had an indication or was safe and effective for use for anything other than back -- or excuse me, cancer pain?
A. Correct. But this statement that I made talks about market potential, and it is based on clinical trial results.
Q. We will get to that. You say then: (Reading) Stacey Beckhardt, a Cephalon spokesman, said Monday -- and then it states -- the company estimates that the cancer pain market includes 800,000 people (end of reading).
Do you see that?
A. Yes.
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. (Reading) Cephalon says the number of people with moderate to severe

chronic pain conditions, such as neuropathic pain or back pain, could be two million to three million people (end of reading).
Do you see that?
A. Yes.
Q. So what you're saying here to the people who are reading this, the investors, potential investors who are reading this, is that if the FDA just approves your supplemental application for neuropathic pain and treatment of back pain, and things like that, you can triple to almost quadruple the market; correct?
MR. JAMES: Objection.
THE WITNESS: We could increase the market based on those indications if the FDA approved it, because it was based on clinical trials that we did specifically in those indications.
BY MR. CARTMELL:
Q. Okay. I understand. But let's just make it clear to the jury: The FDA was given those clinical trials and the FDA denied your application; correct?
A. The FDA also said that the product was efficacious in those conditions.

Q. Yeah, but it said they couldn't approve it because they couldn't be convinced that it was safe as far as whether there would be abuse, misuse, and diversion; correct?
A. That is what the Agency stated.
Q. Okay. But what you're saying to investors here is, we're going to try to get a broader indication. We're going to try to get the FDA to allow us to prescribe this to not only cancer patients, because the cancer pain market is only 800,000 people -- but if we can now sell it to back pain patients, and we can sell it potentially to neuropathic pain patients, we could possibly have a market of two to three million people; correct?
MR. JAMES: Objection.
THE WITNESS: We also know that 74 percent of those patients experience breakthrough pain.
MR. CARTMELL: Okay. I'm going to object and move to -- see what's happening here is you're just trying to insert what you want to say. And I'm fine, but you've got to answer the questions I'm asking. And your counsel will get a chance to ask you questions after that. Okay?
So let me restate my question real quick. And I'm not trying to be aggressive or mean. But I

just want to make sure the record is clear on answers to my questions.
Q. But what you're saying to investors here is, we're going to try to get the FDA to allow us to prescribe this to not only cancer patients -- because the cancer pain market is only 800,000 people -- but if we can now sell it to back pain patients and we can sell it potentially to neuro pain patients, we could possibly have a market of two to three million people; correct?
A. Correct.
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. And that's four times the size of the cancer pain market; correct?
MR. JAMES: Objection.
THE WITNESS: Not four times by my math. It is larger, but it's not four times by my math.
BY MR. CARTMELL:
Q. It's almost four times. It's between three and four times; is that fair?
A. Yes.
Q. Okay. Ms. Beckhardt, I want to talk to you about back in early 2000s, when you were involved sometimes with marketing and with the PR of

the narcotic Actiq.
Do you recall at that time that you would do an annual PR strategy document?
A. That's correct.
Q. Okay. And the Marketing Department would also do annual marketing plans; is that right?
A. That's correct.
Q. And I noticed from the internal documents that were produced from your custodial file that you were on the team that would actually review the drafts of the marketing plans as they were being developed?
A. I did not have a -- I was on the teams, but I did not approve the marketing plan.
Q. I understand. I should have said, and I apologize, you were on the team that would review the drafts of the marketing plan; correct?
A. I would see the drafts, yes.
Q. And also from time to time you would be asked by the Marketing Department to contribute to and write a portion of those plans; correct?
A. Related to my responsibilities and public relations.
Q. Right. And the marketing plans for the company, even though you weren't in the Marketing

Department, actually incorporated your PR strategy into the marketing plans; correct?
A. It was a cross-functional plan. So yes.
Q. And early on with Actiq, Cephalon had a strategy, a marketing strategy, related to trying to convince doctors to prescribe Actiq for not only cancer pain but also for all types of other pain, like headaches or migraines or back pain or chronic pain; correct? Do you remember --
MR. JAMES: Objection.
THE WITNESS: No, I do not remember. And what I do remember is that there was not any effort ever to prescribe to just chronic pain patients who were --
MR. CARTMELL: Okay. I'm going to object to the answer after you don't remember. And I will ask it again.
Q. And early on with Actiq, Cephalon had a strategy, a marketing strategy, that related to trying to convince doctors to prescribe Actiq for not only cancer pain but also for all types of other pain, like headaches or migraines or back pain or chronic pain; correct?
A. I don't recall.

MR. JAMES: Objection.
BY MR. CARTMELL:
Q. You do recall -- and we've just looked at -- that the company told the FDA that it would do its best and take reasonable steps to ensure that Actiq was only used in the intended group of cancer patients; correct?
A. That's correct.
(Exhibit No. 12 was marked.)
BY MR. CARTMELL:
Q. I'm going to hand you what has been marked as Exhibit 12, which is an internal marketing plan that was produced to us from the internal files in this litigation. And this is the Actiq 2002 marketing plan.
I want to go through this with you. But I noticed from documents in your file that, in fact, you contributed in part to drafting the public relations sections of this document; would that be consistent with your memory?
A. I don't remember. But it would be consistent with what likely would have happened.
Q. Okay. And on the front it talks about -- or it mentions P. Andrew Pyfer, Product Manager, Actiq; correct?

A. Yes.
Q. Who was Mr. Pyfer? When it says, "Product manager," where was he on the totem pole as far as the Actiq team?
A. He was the marketer, head marketer, for Actiq at that time.
Q. So did he have direct reports to him?
A. At that time, no. But subsequently, yes.
Q. Okay. So we're in 2002. And Actiq has been on the market for, at the time this was drafted, probably not even a year; correct? Or strike that.
We're in 2002. And as of this time, Cephalon has only been selling Actiq probably for less than a year; is that right?
A. That would be right.
Q. And this marketing plan has included in it marketing strategies that the company had; correct?
A. Yes.
Q. And it also has marketing tactics that the company intends to use; correct?
MR. JAMES: Objection.
THE WITNESS: It has a summary of tactics.

BY MR. CARTMELL:
Q. Let's look actually at the inside cover. There's the table of contents. Do you see that?
A. Yes.
Q. And you see that there's things like SWAT analysis, key marketing issues and development needs; right?
A. Yes.
Q. Product vision and positioning; do you see that?
A. Yes.
Q. What does it mean to position a product?
MR. JAMES: Objection.
THE WITNESS: Positioning relates to putting -- explaining to the marketplace what a product is.
BY MR. CARTMELL:
Q. And then it talks about the marketing and promotional strategy, as we talked about; right?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. Do you see that?
A. Yes.

Q. And then there's the tactical plan that's going to go along -- those are the tactics that will be used by the company to enforce the strategy; is that right?
A. Tactics to support the strategy, yes.
Q. And will you agree with me, Ms. Beckhardt, that this is the document that was produced by the Marketing Department on a yearly basis; right?
A. This is a document -- there were documents on a yearly basis. They did not always look like this.
Q. Okay. But as far as a marketing plan -- and I think it changed later to a brand plan; is that right?
A. Brand plan. Changed format. Changed some of the information that was included, yes.
Q. But if -- if we wanted to go to the document in the files at Cephalon that would tell us what the strategy Cephalon had to market and promote Actiq, this is the document we would go to; correct?
MR. JAMES: Objection.
THE WITNESS: It's a document that the marketers produced.
///

BY MR. CARTMELL:
Q. Right. And this is sort of the playbook of the strategy and the tactics that are going to be used to promote Actiq for that year?
MR. JAMES: Objection.
THE WITNESS: For that year, yes.
BY MR. CARTMELL:
Q. Now, this is confidential; is it not?
A. Marketing plans are confidential.
Q. Who gets to see these marketing plans within the company?
MR. JAMES: Objection.
THE WITNESS: Who gets to see -- in terms of -- I'm not sure I understand what you're --
MR. CARTMELL: That was a bad question.
Q. Are there certain people who get to review these and certain people who don't?
MR. JAMES: Objection.
THE WITNESS: Yes. I mean, you're not going to have the entire company review your marketing plan. And it would be distributed to those people who have expertise in marketing or expertise in a particular tactic that was included in the marketing plan.
///

BY MR. CARTMELL:
Q. So, for example, the sales force, the people in the company who were going to doctors' offices and talking to doctors about the products, would they get to see this plan?
A. No.
Q. Okay. Why is it that the sales force wouldn't get to see this document?
MR. JAMES: Objection.
THE WITNESS: Because the marketers set the strategy. The sales force are implementers.
BY MR. CARTMELL:
Q. Okay. Now, Cephalon had told the FDA, as we just went through, that it was only going to market and promote Actiq to a small group of doctors who treated cancer breakthrough pain, and only market and promote this to doctors that it was to be used for breakthrough -- breakthrough pain in cancer patients; right?
MR. JAMES: Objection.
THE WITNESS: That's what the label said, yes.
BY MR. CARTMELL:
Q. But let's look at what the strategy was for this year. And if you turn to page 2,

please. There's an Executive Summary, and it starts with the review of the prior year; is that right?
A. Yes.
Q. And it looks like, if you look at the number of prescriptions, when Cephalon started marketing and promoting this product Actiq, there were 21,823 prescriptions; do you see that?
A. Yes.
Q. And then 2001 Cephalon increased that, at this time of this plan, to 37,428; do you see that?
A. Yes.
Q. And then the projected for that year was 71,017; do you see that?
A. Yes.
Q. That's a 325 percent increase in one year; isn't it?
A. It is a -- I can't do the math off the top of my head, but that's probably about right.
Q. And then if you look at the numbers, when they started -- Cephalon started promoting this in 2000, before that, it was a $16 million a year in revenue drug; correct?
A. That's correct.
Q. And projected by the end of 2001,

that was going to be -- or Actiq was going to be a $50 million drug; correct?
A. Yes. And when we first acquired the drug, there was very little available -- understanding and familiarity with breakthrough pain.
Q. But that jumped from 16 million to 50 million in one year. That's a 316 percent increase; isn't it?
A. That's what it indicates.
Q. The second paragraph states:
(Reading) Anesthesiologists, pain specialists, are the second largest segment of the Actiq prescriber base behind oncologists and will be the largest by the end of 2001. They have proven to be the most receptive segment and have most readily adopted Actiq as a viable treatment option for breakthrough pain in both malignant and nonmalignant patients (end of reading).
Do you see that?
A. I see that.
Q. So right away this summary of this -- in this strategy document for marketing, they are

talking about a group of doctors that Cephalon already knows is willing to prescribe Actiq not only to cancer patients who are the appropriate selection of patients, but also to noncancer patients; correct?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. That's what it says?
A. That is what it says.
Q. It says:
(Reading) They have also utilized Actiq in the treatment of episodic pain, a substantial segment of the pain market (end of reading).
Do you see that?
A. I see that.
Q. And episodic pain, we already talked about that, that is something that is not indicated for Actiq? Actiq is not indicated for use in episodic pain; correct?
A. That's correct.
Q. If you go down to the 2002 commercial objectives. And let me ask you first, what does it mean, "Commercial objectives"?
MR. JAMES: Objection.
THE WITNESS: The goals of the commercial

team.
BY MR. CARTMELL:
Q. And commercial team means sales; correct?
A. The commercial -- it's the goals that the marketing team is setting.
Q. Setting for sales; correct?
A. Yes.
Q. It says:
(Reading) In 2002 Actiq will be positioned as the most rapid-acting, noninvasive opioid available affording patients personal pain control for both breakthrough pain and episodic pain (end of reading).
Do you see that?
A. I see that.
Q. The company Cephalon had just committed to the FDA that it was going to try its best to ensure that Actiq was only used in patients with cancer; correct?
A. Yes.
Q. But right here, six months later, they are already saying that they want to position Actiq as the product that can be used not only for

breakthrough cancer pain but also for off-label use episodic pain; correct? That's what it says?

A. It's what it says.

Q. If you go down, it says:

(Reading) Without a solid Phase 4 case series, publications plan to support the use of Actiq in other pain types, we will be severely limiting its potential growth in the chronic pain market, a market with a large, unmet need for a rapid-acting, noninvasive opioid (end of reading).

Do you see that?

A. I see that. And what that is saying is that we needed to do studies to better understand that marketplace, because we believed that there was a medical need in other patient populations.

Q. Right. We will talk about that because there's a section in here about why they need studies, in a minute.

If you turn the page, though -- and, actually, I want to go to page 5, if you don't mind. There's a section at the bottom called, "Why Actiq?"

Do you see that?

A. Yes.

Q. It says, "Actiq's clear feature is its rapid onset of analgesia"; right? That's true, isn't it, it was going to be one of the messages that your Marketing Department and potentially you as the PR person was going to send out about an advantage of using Actiq; correct?

A. It's medically correct.

Q. Okay. I want to direct your attention to the sentence:

(Reading) Additionally, due to Actiq's rapid onset, it has a clear and distinct advantage over other products in the treatment of episodic or recurrent pain, for example, sickle cell crisis migraine headaches (end of reading).

Do you see that?

A. I see that.

Q. Those are all off-label uses of this drug; correct?

A. That's correct.

Q. "This type of pain represents a substantial market opportunity"; do you see that?

A. I see that.

Q. Six months after telling the FDA that

you were committed to trying to make sure your drug, dangerous opioid potentially, was only used in cancer patients, the marketing strategy is saying there's an opportunity to sell it in off-label uses, including migraine headaches and sickle cell; correct? That's what it says?

MR. JAMES: Objection.

THE WITNESS: It says that there's a market potential.

BY MR. CARTMELL:

Q. For off-label uses; correct?

A. It says it has a distinct advantage in those treatments -- in those areas.

Q. Okay. But that wasn't my question. I apologize if I wasn't clear.

It says that it has a marketing opportunity, and we discussed a marketing opportunity means an opportunity for more prescriptions; correct?

A. That's correct.

Q. And it's talking about a marketing opportunity or more prescriptions potentially in off-label sales, like headaches, migraines, and sickle cell; correct? That's what it says?

A. That's what it says.

Q. If you then turn to page 28. At page

28 of this marketing document that talks about the strategy to be used with Actiq, under Actiq's potential it more clearly defines in dollars the potential, in fact, if the company can sell Actiq for not just cancer patients but for episodic pain patients; correct?

A. For both breakthrough pain and episodic pain.

Q. (Reading) Rapid pain relief is a largely unmet need in patients suffering from both breakthrough cancer -- or excuse me -- breakthrough pain -- it doesn't say cancer -- and episodic pain. These types of pain represent a substantial market opportunity. The total market for pure, short-acting opioids and combination products has been 753 million in 1999 and 872 million in 2000 and is 568 million year-to-date through July of 2001 (end of reading).

Correct?

A. It states that we were not a short-acting opioid or a combination product.

Q. Right. So --

A. That's a statement of context, where it is not representative of our product.
Q. I understand. But it's talking about Actiq's potential, isn't it, ma'am?
A. It is talking about that is the market for pure, short-acting opioids and combination products. It is not saying that the full market opportunity would be to replace those products.
Q. At any rate, what it's saying is there's potential for Actiq to get into the bigger prescribing market if it goes off label; correct?
MR. JAMES: Objection.
THE WITNESS: It would be the case that if it was prescribed off label, it would be a bigger market of patients who are opioid tolerant.
BY MR. CARTMELL:
Q. If you turn to page 29, there is discussion about having studies like you said. And if you look under recommendations -- and just to put this in context, Ms. Beckhardt, if you go to the prior page, this is under the section titled, "Actiq Development Needs." Do you see that?
A. Yes.
Q. And so this is the section where the company is talking about some things that the

Marketing Department and the company need to do and develop in order to help better market the product; correct?
A. Development needs refer typically to clinical development of a product.
Q. Okay. And when you say "clinical development," you're talking about studies; right?
A. Correct.
Q. Okay. And one of the things that you know from your experience in the industry, is that if there are studies done on a product and you can have those studies published or presented to doctors, that evidence that's produced from that study may help with prescribing of the drug, for example; correct?
MR. JAMES: Objection.
THE WITNESS: A company can't promote on those messages, but the medical community may read those documents, yes.
BY MR. CARTMELL:
Q. Right. In this sentence, under "Recommendations: Minimal needs to continue to grow the business" -- and growing the business means expanding the prescriptions, expanding the sales, making more profits; correct?
A. That's correct.

Q. It states, "Case series" -- or excuse me, let me go up.
(Reading) To continue this growth in 2002, minimal needs must be met, including case series development in noncancer pain models, such as chronic back pain, RSD, sickle cell disease, migraine headaches, et cetera (end of reading).
Do you see that?
A. Yes.
Q. Now, the company is talking about here that it's going to do studies in off-label uses, like migraines and back pain; correct?
A. It's a very common phenomenon when you have a product introduced for a particular indication that a company would do additional studies in a different -- to assess whether or not it was appropriate to use it medically in other indications.
Q. I understand that. And what -- as a strategy, and we will see it later in this, for the company, why that's in the marketing part of the company is because those studies can be used to help market Actiq; correct?
MR. JAMES: Objection.

THE WITNESS: They can be published and they can be part of the literature. There's not -- they are not something that the company should be actively promoting on.
BY MR. CARTMELL:
Q. I understand. But once those are done and published and they are out there, the fact that they are out there can help them potentially get prescriptions for off-label uses; correct?
MR. JAMES: Objection.
THE WITNESS: If a prescriber decides to, at their discretion, follow those new studies, yes.
BY MR. CARTMELL:
Q. And then if you turn to page 31, I want to talk about the Actiq positioning. You told the jury what positioning means; correct?
A. Yes.
Q. It states:
(Reading) Current physician use of Actiq suggests that Actiq has great potential beyond the treatment of breakthrough cancer pain (end of reading).
Do you see that?
A. Okay. Yes, I see that. Thank you.

Q. Okay. So that's -- what that's saying is that if we can expand, meaning Cephalon can expand, beyond the indicated use, the FDA approved use of breakthrough cancer pain, there's great potential for this drug; correct?

A. There's more potential for use, yes.

Q. More potential for money, too; right?

A. Yes.

Q. And if you go down to the positioning statement, it says:

(Reading) The 2002 positioning statement for Actiq reflects that these -- reflects these key differentiating factors. Actiq is a medication in a unique oral transmucosal delivery system that provides the most rapid onset of analgesic of any noninvasive opioid formulation available and affords patients personal pain control for breakthrough pain or episodic pain (end of reading).

Do you see that?

A. Yes.

Q. So with only a matter of months after

entering into commitments and agreements and a Risk Management Program with the FDA that told the FDA your company would do whatever it could to ensure that Actiq was only used in cancer patients internally, inside the files of the company, the strategy was going to be to position Actiq for use in off-label uses like episodic pain; correct?

MR. JAMES: Objection.

THE WITNESS: That's what it states.

BY MR. CARTMELL:

Q. Let me ask you this: Were you involved in this?

A. No.

Q. Do you think it's appropriate?

MR. JAMES: Objection.

THE WITNESS: I'm not a marketer.

BY MR. CARTMELL:

Q. If you turn to page 33. Page 33 is where this part of the plan starts with marketing strategy. So if we read beyond page 33, we can determine what the strategy of the company is going to be; correct?

MR. JAMES: Objection.

THE WITNESS: Commercial strategy.

///

BY MR. CARTMELL:

Q. Commercial strategy being how it's going to be sold?

A. It relates to marketing strategies, yes.

Q. Strategies and the messages, for example, that will be sent, that type of thing, or the tactics that will be used?

A. From a commercial standpoint.

Q. Okay. If you go to page 35, I want to talk about the section on clinical data. And as we discussed, one of the things the company wanted is they wanted to get studies done in noncancer uses; correct?

A. That is correct.

Q. Because that was going to give them a potential -- like you said, potential opportunity to grow the number of prescriptions into off-label indications; correct?

A. That is correct.

Q. It states:

(Reading) There is substantial opportunity for Actiq in the treatment of breakthrough pain in opioid-tolerant patients in a variety

of pain diagnoses, not only breakthrough cancer pain, as well as episodic pain and other disease states. In order to continue Actiq's growth outside of the cancer patient population, Actiq's safety, efficacy, and true onset of an analgesic effect must be demonstrated in other large segments of the pain market, for example, chronic back pain, RSD (end of reading).

Which is reflex sympathy dystrophy?

A. Sympathetic dystrophy.

Q. Reflex sympathetic dystrophy, that's another pain condition; correct?

A. Yes, it is.

Q. Fibromyalgia, that's a chronic pain condition, correct?

A. That's correct.

Q. Migraines, and sickle cell disease; correct?

A. Correct.

Q. And the plan of the company internally, internally the plan is to try to grow in off-label prescriptions by getting clinical data to

support that; correct?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. That's what it says?
A. The plan was to get clinical data to support an understanding of the use -- the safe and appropriate use of these medications in additional indications.
Q. Outside of cancer; right?
A. Yes.
Q. Even though there was no approval that this drug Actiq was safe and effective with any of those indications, not chronic back pain, not RSD, not fibromyalgia, not migraine headaches, and not sickle cell disease; correct?
MR. JAMES: Objection.
THE WITNESS: Research is done in additional indications. We already had demonstrated its efficacy in cancer. So the research that was needed was in other conditions.
BY MR. CARTMELL:
Q. But the point is this, Ms. Beckhardt. Research done is fine, if it's appropriate to be done. But this is a marketing strategy document. And if the research is being done simply so that you

increase the market into off-label usage, that's not appropriate; is it?
MR. JAMES: Objection.
THE WITNESS: I'm -- not my place to say that.
BY MR. CARTMELL:
Q. Let's turn to the tactical plan on page 37. Now, the tactical plan, that's the tactics that the Marketing Department and, in fact, your department, the PR Department, are going to employ to try to promote and market the product Actiq; correct?
A. I did not promote the product.
Q. Let me restate that, then.
The tactical plan is going to be the actual tactics that will be used by Cephalon to enforce the strategy that we have just talked about; correct?
A. That's correct.
Q. And the marketing company is going to employ -- the marketing side of the company is going to employ certain tactics to help market and promote the product; correct?
A. That's correct.
Q. And PR, you in the PR Department, you're also going to be involved in certain tactics as well; correct?

A. That's correct.
Q. It states:
(Reading) The most significant change in the position of Actiq in 2002 is the incorporation of episodic pain as a segment of the targeted pain market (end of reading).
And as we discussed, episodic pain, that's an off-label usage of Actiq; correct?
A. That's correct.
Q. (Reading) Actiq will be positioned to greatly expand use in both the breakthrough pain and the episodic pain segments of the pain market by employing -- by applying the key messages listed above (end of reading).
Do you see that?
A. Yes.
Q. So this is an internal strategy -- an internal strategy to promote off label; correct?
MR. JAMES: Objection.
THE WITNESS: It's an internal strategy that acknowledges the potential market outside the approved indication.

BY MR. CARTMELL:
Q. Well, it's talking about trying to position it, take -- take actions to position it -- right? -- into areas of off-label usage; correct? That's what it says?
A. That's what it seems to suggest, yes.
Q. And that is directly contrary to what the company had told the FDA; correct?
MR. JAMES: Objection.
THE WITNESS: It is contrary to the Risk Management Program.
BY MR. CARTMELL:
Q. Let's move to page 39. I want to ask you about this -- what would you call this -- tactical plan overview? What is that called? It's a diagram, I guess; is that right?
A. That's a legitimate description of it.
Q. Okay. So this has here the different sides of the company or departments in the company. It has the sales part of the company on the left; right?
A. Yes.
Q. And then it has the Marketing Department in the middle; right?

A. Uh-huh.
Q. And then there is actually, I believe, on here somewhere, indirect promotional. Is that you?
A. That is -- that includes a broad array of nondirect to -- nondirect contact with physicians or other prescribers. So, for example, journal advertisements; that's something that's indirect. A prescriber may or may not see that prescription; as opposed to marketing direct campaigns, there's a direct interaction with the health-care professional.
Q. I see. And so some of those things, like journal advertisements, Internet activity, website for CME, and things like that, you were involved in some of those activities; correct?
A. No, I was not.
Q. Okay. At any rate, one thing I want to point out here, it says "CME programs." Do you see that?
A. Yes.
Q. In the middle. That's continuing medical education?
A. Yes.
Q. That's under marketing promotional.

Do you see that?
A. Yes.
Q. So the company knows; right? Internally this is their sort of internal sort of playbook? The company knows that those continuing medical education programs are actually marketing promotional tactics; correct?
MR. JAMES: Objection.
THE WITNESS: I don't know why that it would be listed as a market product -- marketing tactic, because they were not led by the Marketing Department.
BY MR. CARTMELL:
Q. Okay. But it's listed in their internal document that way; is it not?
A. I see it there, but I don't understand why it's that way.
Q. You wouldn't have put it there?
A. I would not have put it there.
Q. Take a look at -- if you would, at page 43. And this is where I think you come in, as far as your involvement in public relations. It states:
(Reading) Public relations plan: The primary goals of the 2002 Actiq public

relations plan are to increase awareness of breakthrough pain and Actiq among targeted physician and patient populations (end of reading).
Do you see that?
A. Yes.
Q. And -- and you're talking about targeting physician and patient populations. There are specific targets that your company had, as far as physicians, for example, who you were going to target your messages and your marketing and promotional activities to; right?
MR. JAMES: Objection.
THE WITNESS: The -- the commercial side of the business did. I did not.
BY MR. CARTMELL:
Q. Okay. And then there was also patient populations, that you targeted certain parts of the patient population that you wanted to target as far as getting your messages out to them; correct?
MR. JAMES: Objection.
THE WITNESS: We worked with patient advocacy groups, but we did not work -- do any work direct to patient.
///

BY MR. CARTMELL:
Q. But you wrote this; didn't you?
A. I understand. I don't know if I wrote -- I probably wrote some of them, because it talks about public relations. But we were not talking about getting direct to patients. We talked about patient support organizations. And that's different than going direct to patient.
Q. It then states --
A. We did no direct-to-patient communication.
Q. So is what you're saying -- just so I'm clear, are you saying that, for instance, you might deal directly with, for example, a professional society or -- what did you call them, a patient group?
A. That's correct.
Q. And then they would distribute the information to the patients directly; correct?
MR. JAMES: Objection.
THE WITNESS: At their discretion.
BY MR. CARTMELL:
Q. Right. It then states, "The targeted patient populations" -- so you've got a patient population that you're going to target -- "will be

both cancer patients and chronic nonmalignant pain patients." Do you see that?
A. Yes.
Q. So in 2002, in the Public Relations Department, you have already decided that you're not only going to target for your message cancer patients, but you're also going to target noncancer patients for your messages; correct?
A. That's what it states.
Q. And that -- those messages going to those people, if they get the prescription, these noncancer people, that's off label; correct?
A. Yes. But this document continues to say that cancer patients will be the primary focus.
Q. Okay. And I'm not arguing with you about that. But the fact of the matter is, in 2002, you and your department, public relations, had decided that you weren't going to limit your -- excuse me, your activities and tactics to just cancer patients, you were going to expand it to noncancer patients; correct?
A. As led by the marketing strategy.
Q. Right. Are you saying that as led by Andy Pyfer, at his direction, you had to expand it beyond cancer patients to noncancer patients?

A. Andy was the head of marketing at that time.
Q. And you felt comfortable doing that?
MR. JAMES: Objection.
THE WITNESS: I was following the marketing strategy. And I felt comfortable if the patients were already taking opioids.
BY MR. CARTMELL:
Q. So it's clear for the jury, I just want to make sure that they understand your testimony. As of the time you were sending messages to -- and honestly through other organizations to patients all over America, for example, about breakthrough pain or about Actiq, your feeling was that if they were already on another opioid, you felt comfortable that you could present your marketing messages to them even if they were not cancer patients; is that what you're saying?
MR. JAMES: Objection.
THE WITNESS: I did not provide information to those organizations specifically about the product. It was mostly disease awareness. And disease awareness, we did do breakthrough pain awareness in both cancer and noncancer populations.
///

BY MR. CARTMELL:
Q. Right. Knowing full well, right -- you knew and the company knew, that if, in fact, those patients went to their doctors and said, I have breakthrough pain, and I don't have cancer, but I want a drug, knowing full well that if they were put on your drug, Actiq, that would be off-label usage; correct?
MR. JAMES: Objection.
THE WITNESS: If prescribed by the physician, yes.
BY MR. CARTMELL:
Q. And you knew full well that the company had committed to the FDA that they were not going to take affirmative actions to try to have this drug overused and used for off-label purposes; correct?
MR. JAMES: Objection.
THE WITNESS: The commitment was not to use it in an off-label manner.
MR. CARTMELL: Let's take a break.
MR. JAMES: Yes.
THE VIDEOGRAPHER: We are going off the record. The time is 3:06 p m.
(Recess taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 3:26 p.m.
BY MR. CARTMELL:
Q. Ms. Beckhardt, we are back on the record after a short break. Are you ready to proceed?
A. Yes.
Q. We're talking about the 2002 marketing plan from Cephalon; correct?
A. Yes.
Q. And we have gone through several of the provisions in that marketing plan that was put together by Mr. Pyfer, and parts of it, the public relations part, put together by you; correct?
A. Correct.
(Exhibit No. 13 was marked.)
BY MR. CARTMELL:
Q. And I want to hand you what's been marked as Exhibit 70 -- or excuse me, Exhibit --
MR. JAMES: 13.
MR. CARTMELL: -- 13.
Q. Let me hand you what's been marked as Exhibit 13. And really this is for demonstrative purposes, Ms. Beckhardt. And you have looked at both Exhibit 7, the Risk Management Program document for

Actiq from 2001.
You know what, I gave you the wrong -- I gave you the wrong one, I think. This is 2003?
Okay. I gave you the 2003. I gave you the wrong one. You can hold on to that.
A. Okay.
(Exhibit No. 14 was marked.)
MR. CARTMELL: I'm going to give you Exhibit 14 first. Now I see. Sorry. I'm very confused.
I'm going to hand you Exhibit 14, which is for demonstrative purposes.
THE WITNESS: Thank you.
BY MR. CARTMELL:
Q. I've handed you Exhibit 14, Ms. Beckhardt. And this is for demonstrative purposes. And I want to ask you a few questions about this. But you've looked at the Risk Management Program for Actiq that the Cephalon entered into with the FDA in 2001, which is Exhibit 7; correct?
A. Yes.
Q. And we just got done looking at the internal marketing plan for Cephalon from 2002; correct?
A. Correct.

Q. And I'm putting this up here for the jury to sort of compare and contrast what Cephalon was telling the FDA in 2001 related to its obligations and the messages that it planned to send to physicians and pharmacists and nurses related to safety issues with Actiq. And then internally what Cephalon was saying its marketing strategies will be; okay?
A. Yes.
Q. Okay. And as you can see here, in 2001, as we know, the company was telling the FDA that it was going to send messages and do what it could for the safety of patients to ensure proper patient selection. And one of those messages was going to be that Actiq is specifically indicated solely for the treatment of breakthrough cancer pain in chronic opioid-tolerant cancer patients.
Do you see that?
A. Yes.
Q. But you now know, from going through the 2002 marketing plan, that internally the Marketing Department had a strategy that was inconsistent with that; correct?
MR. JAMES: Objection.
THE WITNESS: It was inconsistent, but it

should be clear that these were not intended to replace the around-the-clock medications. These were in opioid-tolerant patients. This would have been a medication in addition for patients who were experiencing breakthrough pain.
BY MR. CARTMELL:
Q. No. I understand that. And really the point that I am focusing on is the company was telling the FDA and committing to the FDA that it was going to help the FDA limit the use of this product to only cancer patients; right?
MR. JAMES: Objection.
THE WITNESS: Yes.
BY MR. CARTMELL:
Q. But internally the company was creating or had created a strategy to expand the usage of the Actiq beyond just cancer patients; correct?
A. Based on clinical data.
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. Right. And it was planning to expand the usage into chronic back pain, RSD, fibromyalgia, migraine headaches, sickle cell disease? That's what it says; correct?

A. That's what it says.
Q. And you would agree with me, would you not, that what the company was doing, the Marketing Department, the strategy that it had, what it was doing, trying to expand the usage of Actiq, was inconsistent with what it was telling the FDA; correct?
MR. JAMES: Objection.
THE WITNESS: It's inconsistent with what is in the Risk Management Program.
BY MR. CARTMELL:
Q. And what's in the Risk Management Program are obligations that they took on, that Cephalon took on in order to sell this product; correct?
MR. JAMES: Objection.
THE WITNESS: The Risk Management Program was part of the approval process.
MR. CARTMELL: I want to look at one more section in the 2002 marketing plan, if you don't mind, ma'am.
Q. If you would look back at the Exhibit 12 -- we didn't look at this, but I'd like you to take a look at it. But let me ask you a question first: CME programs, continuing medical

education programs, that's what that stands for; right?
A. Correct.
Q. And you saw that in the marketing plan from 2002, Cephalon had listed those programs as promotional in nature; correct?
A. I'm not sure why they were listed in that manner.
Q. I know. But you saw that that's the way they listed it; correct?
A. Correct.
Q. And it wouldn't be appropriate, would it be, for a company like Cephalon to enter into continuing education, medical education programs, solely to get around the restrictions that were imposed by the RiskMAP; would it?
MR. JAMES: Objection.
THE WITNESS: I'm not in a position to answer that.
BY MR. CARTMELL:
Q. But would you agree with me that if the company decided that it wanted to just do medical education programs because it was restricted from having its sales rep go in on an off-label market, that wouldn't be appropriate; correct?

MR. JAMES: Objection.
THE WITNESS: If -- if that was the sole purpose, and the information presented was not medically accurate and wasn't intended for education, that would be a problem. But if the CME program was intended for education, was medically appropriate, you know, that's not for me to say.
BY MR. CARTMELL:
Q. Okay. Turn to page 40, if you would. This is Cephalon's playbook and marketing strategy as of 2002, and it lists CME programs, peer-to-peer educational programs. That's what those are, right?
A. No, they are -- peer-to-peer educational programs may be CME, but they may not be CME.
Q. I understand. But it talks here about peer-to-peer educational programs such as CME can be tremendously effective marketing. Do you see that?
MR. JAMES: Objection.
THE WITNESS: Yes, I see that.
BY MR. CARTMELL:
Q. So the company Cephalon is considering that these medical education programs, where doctors speak to other doctors, those are

tremendous marketing opportunities for this company. That's what Cephalon is saying; correct?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. Do you see that?
A. It is true that the CME -- a tactic of using CME programs was included in this plan.
And it's saying that actually from a marketing perspective, it's tremendously effective; right?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. That's what it says at the end of the first sentence?
A. Yes, that's what it says.
Q. If you go to the second sentence, it says:
(Reading) The primary reason CME programs will be largely employed in 2002 is due to the limited promotional flexibility and ability to make claims that a company's Actiq subpart (h) classification (end of reading).
Do you see that?
A. Yes.

Q. So what that's saying is because of the Risk Management Program, we can't off-label market, but we can have doctors go out there and talk about off-label uses; correct?
MR. JAMES: Objection.
THE WITNESS: It's saying that you can have continuing medical education programs that are not led by the company. And, yes, other doctors will be participating in them and may, given this, suggest -- they may talk about issues that are beyond the label.
BY MR. CARTMELL:
Q. Right. And it says:
(Reading) CME programs allow us to use peer-to-peer medical education to raise awareness of the proper assessment and treatment of breakthrough pain and episodic pain(end of reading).
Do you see that?
A. Yes.
Q. So what that's saying is if they use doctors at medical education programs, they can actually expand the usage and talk about episodic pain, which is off-label; correct?
MR. JAMES: Objection.

THE WITNESS: I can't speak to that because I wasn't involved in those programs.
BY MR. CARTMELL:
Q. I understand. But it's saying that that's the strategy they are going to use in those continuing medication -- medical education programs; correct?
A. That is what it says here.
Q. Okay. And do you agree with me that that is inconsistent with what the FDA wanted?
MR. JAMES: Objection.
THE WITNESS: It is inconsistent with the Risk Management Program.
(Exhibit No. 15 was marked.)
BY MR. CARTMELL:
Q. Right. Let me hand you Exhibit 15. If we look at a contrast and comparison to what the company was telling the FDA in 2001, they were saying they were going to do educational programs to tell about safety messages and to enforce that this product should only be used for cancer patients; correct?
MR. JAMES: Objection.
THE WITNESS: It doesn't mention cancer patients here.

BY MR. CARTMELL:
Q. Yeah, but you know that proper patient selection messages is defined in that, as we discussed earlier, about cancer -- as cancer patients; correct?
A. It also refers to opioid-tolerant patients.
Q. Right. Both; right?
A. That's correct.
Q. So -- but if you look at that and contrast what they are saying internally is they are going to do education programs to promote off-label marketing and promotion; correct?
MR. JAMES: Objection.
THE WITNESS: That is what it states.
BY MR. CARTMELL:
Q. Those two things are wholly inconsistent; correct?
MR. JAMES: Objection.
THE WITNESS: They are inconsistent.
MR. CARTMELL: I want to move to Exhibit 16, which is the 2003 Actiq Marketing Plan.
(Exhibit No. 16 was marked.)
BY MR. CARTMELL:
Q. And I will represent to you that from

documents in your file, I believe you were also involved in drafting a portion of this marketing document related to public relations; would that be consistent with your memory?
A. It would be consistent with what I would have been responsible for. I don't remember specifically.
Q. Okay. Again, if you look at this plan, this is also Andrew Pyfer who was the Director in the Marketing Department at that time; correct?
A. Correct.
Q. But now there's -- there's Christine Wells and Paula Castagno; is that right?
A. That's correct.
Q. Were they added in 2003 to the company or the Marketing Department?
A. Around that time.
Q. Okay. Again, inside cover you look at the table of contents, and I compared them, and essentially it's the same -- or it is the same table of contents from the 2002 plan; is that consistent with your memory of how these plans were typically set up for a number of years?
A. At that time, yes.
Q. Okay. And so this would be the

playbook, so to speak, for the marketing strategy and tactics for the next year or 2003; correct?
A. That's correct.
Q. And if you look at the Executive Summary on the inside, or next page, page 2, again, there now -- strike that.
If you look at the Executive Summary, there's a performance review that is summarizing how the company did or Actiq did in 2002; right?
A. Yes.
Q. It states:
(Reading) Cephalon experienced another extraordinarily successful year with Actiq in 2002. This achievement can be attributed primarily to focused -- excuse me -- and integrated marketing and sales efforts (end of reading).
Do you see that.
A. Yes.
Q. And is that -- was that the feeling at the time, was that the marketing and sales departments were responsible for this amazing and extraordinary, as they say, growth of the Actiq sales?
MR. JAMES: Objection.

THE WITNESS: I -- I don't know.
BY MR. CARTMELL:
Q. They say in 2002 they were projecting -- or they did have -- they were projecting, excuse me, prescriptions that would be 140 percent growth over the previous year. Do you see that?
A. Yes.
Q. Then if you go down to the commercial objectives, that's where internally the company was trying to -- trying to forecast or strategize on the amount of sales and prescriptions that they wanted to have in 2003; correct?
A. Consistent with marketing plans in general, yes.
Q. And it says:
(Reading) The gross sales in 2002 were 133.8 million, and in 2003 they were budgeting a 64 percent increase up to 218.8 million (end of reading).
Do you see that?
A. Yes.
Q. And an increase of 50 percent of prescriptions of Actiq for 185,467 in 2002 all the way up to 279,880 in 2003; do you see that?

A. Yes. Those are prescriptions, but not patients.
Q. And more prescriptions, as we've discussed, is more sales, more profits; correct?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. Correct?
A. Yes.
Q. If you then go back to page 16, please. This is a year later. And just like in 2002, the Marketing Department is talking about things that they needed to do to expand the usage of Actiq; correct?
A. It states, "Clinical needs to expand usage."
Q. And it states, in the middle of the paragraph:
(Reading) The disease states that represent the largest growth opportunities for Actiq include, but are not limited to, osteoarthritis, rheumatoid arthritis, chronic back pain, migraine headaches, complex regional pain syndrome, and postherpetic neuralgia (end of

reading).
Do you see that?
A. Yes.
Q. So, again, a year later in 2003, the company is trying to strategize on how to grow the usage of Actiq outside of cancer into other conditions; correct?
A. Yes.
Q. If you go to -- take a look at Exhibit 13. Once again, this is for demonstrative purposes. I had handed you that earlier. Sorry about that.
Once again, in 2003, a year later, if you look at what the company had told the FDA, and it was obligated to do, as far as making sure that messages were sent and that it was doing everything reasonable to try to make sure this drug was only prescribed to cancer patients with breakthrough pain and that were opioid tolerant, if you look internally at the company, they have got a strategy that is wholly inconsistent with that to try to expand into osteoarthritis, into rheumatoid arthritis, chronic back pain, migraine headaches, complex regional syndrome and postherpetic neuralgia; correct?
MR. JAMES: Objection.

THE WITNESS: The marketing plan talks about conditions that are outside the Risk Management Program.
BY MR. CARTMELL:
Q. And do you think -- or did you think at the time that it was appropriate for the company to be strategizing, from a marketing perspective, to expand the use of Actiq so much outside of the indicated FDA-approved use?
MR. JAMES: Objection.
THE WITNESS: It's not my decision.
BY MR. CARTMELL:
Q. Did you think it was appropriate -- or let me ask it this way. Now, in retrospect, knowing what you know, do you think it was appropriate?
MR. JAMES: Objection.
THE WITNESS: Knowing what I know, seeing the data from three randomized placebo-controlled studies, I would say that there was some legitimate medical need in patients who did not have cancer, and that these products could be administered, at least Fentora that we knew -- we didn't do the studies in Actiq -- it could be administered and effectively administered in other patient populations.

BY MR. CARTMELL:
Q. But do you agree with me that when the FDA told you as a company not to do that specifically, that the company shouldn't have done that?
MR. JAMES: Objection.
THE WITNESS: I was not setting the marketing strategy.
BY MR. CARTMELL:
Q. If you were, would you have thought that it was appropriate to tell the FDA that you were going to limit the use to only cancer patients, do everything you could to make that sure happen, but internally, and your strategy as a company, you were going to go out and try to expand into all these different uses; would you have done that?
MR. JAMES: Objection.
THE WITNESS: I personally would not have done that.
BY MR. CARTMELL:
Q. If you would turn to page 36. Under "Medical Liaison Managers," it states:
(Reading) The medical liaison managers support Actiq in three distinct manners (end of reading).

Tell the jury who medical liaison managers are, please.
A. Medical liaisons are individuals with a medical background who interface directly with non-healthcare professionals.
Q. And were you involved with those activities?
A. No, I was not.
Q. Let me just ask you quickly, though. At the bottom it does say that they were going to develop a case series outside of cancer patients, and that we're doing that to grow Actiq beyond breakthrough cancer pain in 2003 and beyond. Do you see that?
A. It states that.
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. That's another use of studies for promotional purposes to grow off-label sales; correct?
MR. JAMES: Objection.
THE WITNESS: Another opportunity to collect data related to uses outside the label.
BY MR. CARTMELL:
Q. Collecting data is fine; right?

A. Yes.
Q. But using that data to promote and market and grow sales and profits, that's not fine; correct?
MR. JAMES: Objection.
THE WITNESS: If the data are in the public domain in the medical literature, it's for a doctor to determine whether or not they are going to rely on those medicines -- that data.
Is it appropriate to promote on that? It's outside the indication.
BY MR. CARTMELL:
Q. So it's not appropriate; right?
A. That's correct.
Q. And this is saying that it's part of the marketing strategy to use that; correct?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. It's a promotion strategy, at least by the Marketing Department in its internal document; correct?
MR. JAMES: Objection.
THE WITNESS: It is part of the -- it is listed as part of the marketing strategy.
///

BY MR. CARTMELL:
Q. Turn to page 39, please. This is another section in 2003, a year later talking about Actiq's potential. Do you see that?
A. Yes.
Q. And, again, in 2003 it's talking about rapid pain relief is largely unmet need in patients suffering from malignant and nonmalignant breakthrough pain as well as chronic episodic pain, migraine, sickle cell. These types of pain represent a substantial market opportunity.
So, once again, internally, the company is talking about market opportunities of expansion into off-label uses; correct?
A. That is what it says here.
Q. And it's talking about increases in sales from 906 million in 2000 -- or excuse me -- strike that.
And it's talking about increases in the potential market for Cephalon of 906 million in 2000 all the way, in 2002 projected, $1.3 billion market; do you see that?
MR. JAMES: Objection.
THE WITNESS: That's not correct in what it says.

MR. CARTMELL: Oh, I'm sorry. Let me restate it. I was reading the parentheses.

Q. And it says, does it not, that there's $906 million market in 2000, a $1.15 billion market in 2001, and year-to-date, $640 million market, but they were projecting it to be 1.3 by the end of 2002; correct?

A. That is not what it says. It says that is the market potential for pure, short-acting opioids and combination products. We were not a short-acting opioid or a combination product. And we were not intended to replace those products.

Those were the kinds of products that were used for management of breakthrough pain that were not used -- that were shown medically not to be particularly effective.

Q. I understand what you're saying. I appreciate that clarification.

But what we do know is that what this is saying is that part of the strategy was to look at Actiq's potential and to move Actiq into a market that was off-label and it specifically mentions migraine use and sickle cell use; correct?

MR. JAMES: Objection.

THE WITNESS: That's correct.

BY MR. CARTMELL:

Q. And that, just like we've said previously, was wholly inconsistent with what the company told the FDA it would do; correct?

MR. JAMES: Objection.

THE WITNESS: Inconsistent with the Risk Management Program.

BY MR. CARTMELL:

Q. And the Risk Management Program was put in place by the FDA; correct?

A. That's correct.

Q. And the company knew it couldn't sell the product without the Risk Management Program; correct?

MR. JAMES: Objection.

THE WITNESS: That was part of the labeling.

BY MR. CARTMELL:

Q. Turn to page 44 of this 2003 marketing plan, please. As of 2003, though, let me ask you -- actually, the company had told, Ms. Beckhardt, the FDA what it believed should be and what it was going to try to make sure was the proper patients to take this medication; correct?

MR. JAMES: Objection.

THE WITNESS: In the Risk Management

Program.

BY MR. CARTMELL:

Q. Right. And the company told the FDA that proper patient selection or the proper patients for Actiq would be cancer patients with breakthrough pain who were already opioid tolerant; correct?

A. That's correct.

Q. But internally, if you look at their marketing strategy and plan, at page 4, they had a different idea of what a proper patient was for their medication. It states:

(Reading) Patient profile: The ideal patients for Actiq are those that will benefit from Actiq's rapid onset of analgesia as well as its portability, convenience and control. Any opioid-tolerant patient suffering from breakthrough pain or chronic episodic pain, regardless of disease state, are potential Actiq patients (end of reading).

Do you see that?

A. Yes, I see that.

Q. That is an expansion of a patient profile into off-label indications; correct?

A. That is correct.

Q. And that is wholly consistent -- inconsistent -- strike that.

That is wholly inconsistent with what the company told the FDA; correct?

MR. JAMES: Objection.

THE WITNESS: It's inconsistent with the Risk Management Program, yes.

(Exhibit No. 17 was marked.)

BY MR. CARTMELL:

Q. I'm going to hand you Exhibit 17, so the jury can see what the company was telling the FDA in 2001 and their strategy internally what they were doing in 2003; do you see that?

A. Yes, I see that.

Q. In 2001 they told the FDA and the Risk Management Program they were going to send messages and do everything they could to make sure there was proper patient selection, including that Actiq was only used with cancer patients; correct?

MR. JAMES: Objection.

THE WITNESS: Yes.

BY MR. CARTMELL:

Q. In 2003 internally -- they put together a profile internally that they wanted for

their Actiq product, and it included sufferers, any opioid-tolerant patient suffering from breakthrough pain or chronic episodic pain regardless of whether or not they had cancer; correct?

A. That's correct.

Q. Do you think that was appropriate for them to be able to sell this potent opioid product under the guise of a Risk Management Program that they told the FDA they would do everything they could to limit the use to cancer patients, but internally set up a patient profile as part of their marketing strategy that included all kinds of noncancer patients? Do you think that was appropriate?

MR. JAMES: Objection.

THE WITNESS: I was not in the marketing plan. I didn't set those profiles.

BY MR. CARTMELL:

Q. If you were setting those profiles, would you have done that?

A. I would not have set it that way, no, unless it was based on data sets.

Q. And we have already seen in here that they didn't have data sets then; did they?

A. Not at that time, no. There was experience in the community using those -- using --

treating breakthrough pain and noncancer states.

Q. But no randomized, controlled, double blind placebo-controlled studies; right?

A. That is correct. Not at that time.

Q. Turn to page 47, please. Starting in 2003, if you go down to the issue, "Low awareness, lack of branding of Actiq Cephalon within the pain community," it talks at the end of the paragraph about:

(Reading) Marketing will sponsor symposia at the American Academy of Pain Management and possibly (end of reading) --

What's PM&R; do you know?

A. Pain medicine and rehabilitation.

Q. -- (Reading) and possibly pain medicine and rehabilitation meetings on the topic of use of opioids in neuropathic pain and use of opioids in musculoskeletal pain (end of reading).

Do you see that?

A. Yes.

Q. So this is talking about strategies to use to increase the use of Actiq into off-label uses; correct?

MR. JAMES: Objection.

THE WITNESS: Yes. It is -- it does indicate that marketing will sponsor the symposium, but it is my understanding that marketing did not create the symposia. They had the financial -- they had financial support from the Marketing Department, but they did not do the content.

BY MR. CARTMELL:

Q. I understand, but -- but what they were doing, according to their marketing strategy, was they were trying to pay grants or sponsor programs that included off-label messages; correct?

A. That's correct.

Q. And that is inconsistent with the obligations that they had entered into with the FDA; correct?

MR. JAMES: Objection.

THE WITNESS: I'm not sure whether it's inconsistent to support continuing medical education.

BY MR. CARTMELL:

Q. Well, when you tell the FDA that you're going to do all you can to spread the message that the product should only be used for cancer, but then you pay money, grants and things, to put on medical education programs or symposia for off-label

uses, isn't that inconsistent?

MR. JAMES: Objection.

THE WITNESS: It depends on what the content was of those programs. And I don't recall the content.

BY MR. CARTMELL:

Q. Okay. And then I think if you turn to page 55, this is one of the tactics that was used by the company to further their strategy of increasing usage of Actiq into off-label uses. And this is one that you were involved in; correct?

A. Where are you?

Q. Patient education materials and programs.

A. Yes.

Q. It states:

(Reading) marketing and public relations will work together (end of reading) --

So you from time to time worked with marketing; correct?

A. That is correct.

Q. -- (Reading) to create and/or update appropriate patient education materials, both branded and nonbranded

patient education pieces were created in 2002. The focus of 2003 will be to create additional nonbranded patient educational materials.

The Nursing Advisory Board formed in 2002 will help to focus and drive this process. These materials will be created, updated in coordination with professional and/or patient support organizations as necessary and may be applicable across varying disease states and patient populations (end of reading).

Do you see that?

A. Yes.

Q. And so you're creating patient educational materials and programs that don't just deal with cancer, breakthrough pain in cancer patients, but it's going to deal with conditions across varying disease states; correct?

A. With respect to disease awareness, not product usage.

Q. Okay. And we will talk about some of the things you did in that respect. But that's -- those were some of the things you did related to

Actiq and Fentora; correct?

MR. JAMES: Objection.

THE WITNESS: In terms of developing and having a nurse's advisory board and working with patient advocacy groups, yes.

MR. CARTMELL: Okay.

Q. Now, you were on the team that prepared both of these marketing plans; correct?

A. At this time I was not on the teams that created these plans. I was asked to provide input just for the public relations portion.

Q. Okay. You reviewed those plans back in realtime; correct?

A. I reviewed them after they were completed.

Q. Okay. Well, I think you actually created a portion of them related to public relations; correct?

A. I created that portion, and it was -- and it was submitted to them. But I did not see this whole plan prior to its -- its completion.

Q. Okay. Well, based on your review of both of these plans, the 2002 marketing strategy and tactics plan and the 2003 marketing and strategy plans related to Actiq, would you agree with me that

with respect to marketing, and that department, that Cephalon had a marketing strategy to expand the use of Actiq into pain conditions, including back pain, episodic pain, migraines, and other type of noncancer pain? Would you agree with me?

MR. JAMES: Objection.

THE WITNESS: I think there was intent to look at breakthrough pain in those various conditions.

BY MR. CARTMELL:

Q. Okay. I'm not asking about breakthrough pain. You saw multiple occasions where the strategy and tactics were intended to increase the usage of Actiq into off-label uses; correct?

MR. JAMES: Objection.

THE WITNESS: Correct. But those off-label usage were for breakthrough pain, not for the underlying pain condition.

BY MR. CARTMELL:

Q. The distinction you're making is that the company was actually having a strategy to increase into off-label usage, but it was for breakthrough pain uses in noncancer conditions; correct?

A. That's correct.

Q. Still, it's true, is it not, that those were not indicated conditions; correct?

A. That is correct.

Q. And still that strategy called for off-label marketing and promotion; correct?

MR. JAMES: Objection.

THE WITNESS: Yes.

BY MR. CARTMELL:

Q. And this was true even though Cephalon committed to the FDA that it would take all reasonable steps to ensure that Actiq was only used in patients with breakthrough cancer pain; correct?

MR. JAMES: Objection.

THE WITNESS: That is correct.

BY MR. CARTMELL:

Q. Now, let me ask you, did you know back in 2003, in that period of time, that Cephalon was being investigated by multiple different entities related to off-label marketing?

A. In 2003, I do not believe I was aware of that.

Q. At some point, I take it, that you learned that that was the case; is that true?

A. That's correct.

Q. Can you recall specifically or even

generally when that was?
A. I don't remember the date.
Q. Did you know in 2008 that Cephalon actually admitted to breaking the law with respect to the promotion and marketing of Actiq?
MR. JAMES: Objection.
THE WITNESS: I know that in -- that we -- we -- the company admitted to off-label promotion.
BY MR. CARTMELL:
Q. And did you know that back in 2008?
A. I did not know the final decision on any kind of case until after it was made.
Q. Did anyone give you the details of how Cephalon broke the law or what it was they did that they admitted breaking the law, as far as promotion and marketing of Actiq?
MR. JAMES: Objection.
THE WITNESS: I'm not exactly sure what you're referring to.
BY MR. CARTMELL:
Q. Okay. Let me restate that question. It was a crummy question.
Did anyone give you the details of what actions Cephalon took or what tactics they used that were off-label promotion and marketing? Did anybody

tell you that?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. And I'm talking about the tactics they used that they pled guilty to.
MR. JAMES: Objection.
THE WITNESS: I don't recall when I learned the details of the suit.
BY MR. CARTMELL:
Q. Did you ever look at the guilty plea?
A. No, I did not.
Q. Were you involved at all in the investigation by the United States attorneys or the Medicaid fraud units of Cephalon related to the off-label promotion and marketing of Actiq?
A. What do you mean by "involved"?
Q. Well, any involvement. In other words, did you attend meetings relating to it? Were you a part of a media training related to that, or any involvement?
A. Not to my memory.
Q. Did you ever talk to any of the federal investigators?
A. No, I did not.
(Exhibit No. 18 was marked.)

BY MR. CARTMELL:
Q. I'm going to hand you what's been marked as Exhibit 98 -- or excuse me. That's not true. See, I have these numbers on the documents.
MR. JAMES: I was wondering if I had really blanked out there for quite some time.
MR. CARTMELL: I know. Here we are. I hand you what's been marked as Exhibit 18.
THE WITNESS: Okay.
MR. CARTMELL: I was only 80 off.
THE WITNESS: Just a little bit.
MR. CARTMELL: Yeah.
THE WITNESS: Thank you.
BY MR. CARTMELL:
Q. I've handed you Exhibit 18, Ms. Beckhardt, which is a press release that was put out by the Department of Justice in September of 2008 with respect to Cephalon and its guilty plea.
Have you seen this before?
A. I don't remember. I probably did, but I don't recall.
Q. As a director of the PR Department and a spokesperson for the company, you suspect that at some point you probably received this; fair?
A. Probably, yes.

Q. It's titled, "Biopharmaceutical company, Cephalon, to pay 425 million and enter plea to resolve allegations of off-label marketing."
Do you see that?
A. That's correct.
Q. And were you knowledgeable at the time that Cephalon actually did pay 425 million related to the allegations against it for Medicare and Medicaid fraud and off-label promotion?
A. Yes, I was.
Q. Okay. It states:
(Reading) The suits allege that Cephalon engaged in a scheme to market Gabitril, Actiq and Provigil for unapproved uses in violation of the Food, Drug and Cosmetic Act which requires a company to specify the intended uses of a product in its new drug application to the FDA. Once approved, the drug may not be marketed or promoted for so-called off-label usage, any use not specified in application and approved by the FDA (end of reading).
Do you see that?

A. Yes.
Q. A couple paragraphs down it says:
(Reading) The FDA approved Actiq for use only in opioid-tolerant cancer patients. Between 2001 and 2006, Cephalon allegedly promoted the drugs for noncancer patients to use for such maladies as migraine, sickle cell pain crises, injuries and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use with patients who were not opioid-tolerant (end of reading).
Do you see that?
A. I see what it says, yes.
Q. And we just looked at the marketing plans and strategy and tactics that the company was using in 2002 and 2003. And some of the things in those plans are included here, including sickle cell therapy strategy to expand into that use; correct?
A. That is correct.
Q. Do you know whether or not, in fact, this was -- that strategy of off-label marketing was actually engaged in from 2001 to 2006, or was that

something that if it was, you didn't know about?
MR. JAMES: Objection.
THE WITNESS: I was aware there was increased usage of our product in other -- other than cancer.
BY MR. CARTMELL:
Q. Okay. Did you at the time suspect that part of that large increase in off-label usage may be the result of the sales team or the marketing strategy put in place?
MR. JAMES: Objection.
THE WITNESS: I had some suspicions, yes.
BY MR. CARTMELL:
Q. Did you talk to anybody about that, any management, while you were there?
A. Yes.
Q. Who did you talk to about that?
A. My supervisor.
Q. Who was your supervisor at the time?
A. Cheryl Williams.
Q. And what were you told in response to your concerns?
A. I don't recall. But she did not have oversight over the marketing strategy in any shape or form.

Q. Did you ever talk to Mr. Pyfer and tell him that you had concerns that he was instituting a strategy and tactics of off-label promotion?
A. I don't recall.
Q. You may have, you just don't remember?
A. I don't recall.
Q. In retrospect, now knowing that you had suspicions and concerns about the off-label promotion and marketing at the time at Cephalon, do you wish you had done more to try to stop it?
MR. JAMES: Objection.
THE WITNESS: I don't know how to answer that question. I don't know the answer.
BY MR. CARTMELL:
Q. Have you thought about that?
A. No, I have not thought about that.
Q. It states below:
(Reading) Cephalon undertook its off-label promotional practices via a variety of techniques, such as training its sales force to disregard restrictions of the FDA-approved label and to promote the drugs for off-label

uses. For example, the Actiq label stated that the drug was for opioid-tolerant cancer patients with breakthrough cancer pain, to be prescribed by an oncologist or pain specialist familiar with opioids. Using the mantra, 'Pain is Pain,' Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote this drug for many uses other than breakthrough cancer pain (end of reading).
Do you see that?
A. I see that.
Q. And is that part of the suspicion that you had maybe going on with the sales team and the marketing team?
A. I did not have any suspicion that we were marketing to general practitioners.
Q. Okay. But other than that, that's one element here?
A. That is correct.
Q. Other than that, you had suspicions

of what's stated here?
A. Yes.
Q. And is that what you talked to your superior about?
A. Yes.
Q. It states:
(Reading) Cephalon employed sales representatives and retained medical professionals to speak to doctors about off-label uses of the three drugs. The company funded continuing medical education programs through millions of dollars in grants to promote off-label uses of its drugs, in violation of the FDA's requirements (end of reading).
Do you see that?
A. Yes, I see that.
Q. Were you involved in doing any of that?
A. No, I was not.
Q. Is this part of the suspicion you had, though, from the sales or marketing teams, that they were hiring and retaining key opinion leaders or professionals to promote off-label usage?

A. No.
Q. Do you know if this happened, or you just don't know one way or the other?
A. I know that there were physicians who participated in continuing medical education programs.
Q. But you don't know whether or not there were physicians who were hired simply to promote for off-label purposes?
A. I do not know that.
Q. Okay. And then the prosecutor, the main prosecutor from the U.S. Attorney's Office states below:
(Reading) This company subverted the very process put in place to protect the public from harm and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctor's best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA

has approved (end of reading).
Do you see that?
A. Yes, I see that.
Q. And would you agree with me that with that last sentence, that although doctors can prescribe off label, pharmaceutical companies shouldn't have a strategy to influence those decisions or have strategies designed to convince those doctors that the drug being prescribed for the off-label use is safe? Would you agree with that?
A. Are you talking about marketing strategies?
Q. Yes.
A. Yes.
Q. And was that part of actually the suspicion and the concern you had?
MR. JAMES: Objection.
THE WITNESS: At the time that was not my concern because I believed that having represented physicians in a prior position before I came to Cephalon, and working at an academic cancer center, that physicians have the judgment to sort through the information that they're -- that is shared with them.
BY MR. CARTMELL:
Q. Now, knowing what you know and having

worked in pharmaceutical companies, do you suspect that that may happen, that pharmaceutical companies use marketing tactics to convince doctors that the use of off -- excuse me, off-label uses of drugs are safe?
MR. JAMES: Objection.
THE WITNESS: I can't speak to other products. I can't speak to other products.
BY MR. CARTMELL:
Q. But do you suspect that now, knowing what you know, that may have happened with Actiq?
MR. JAMES: Objection.
THE WITNESS: Again, I believe that it is true that we sponsored continuing medical education, and -- but I still would maintain that a physician has the discretion and the expertise to weigh the information that's presented to them.
MR. CARTMELL: How long have we been going?
MR. JAMES: Time for a break.
MR. CARTMELL: Break?
MR. JAMES: Yes, let's take a break.
THE VIDEOGRAPHER: Off the record? We are going off the record. The time is 4:17 p.m.
(Recess taken.)
THE VIDEOGRAPHER: We are back on the

record. The time is 4:46 p m.
BY MR. CARTMELL:
Q. Okay. Ms. Beckhardt, we are back on the record after a break. Are you ready to proceed?
A. Yes.
Q. Okay. I want to sort of switch gears a little bit. And we've talked about your involvement during the Actiq years and the internal strategy from a marketing perspective and some things that you were tasked with to do from a public relations standpoint. But in -- as we discussed previously, in, I believe, September of 2006, Cephalon's new opioid narcotic drug called Fentora came to market; is that correct?
A. Yes.
Q. And we have talked to some other witnesses about this, but I want to make sure it's correct from -- from your memory, and that is that when Fentora came on to the market at around that time, the promotion in marketing by the company of Actiq essentially ceased at that time; correct?
A. At approximately that same time.
Q. Okay. And is it true that the team that was working on Actiq from a promotional standpoint and from a PR standpoint and from a

marketing standpoint, did that team just transition to become the Fentora team?
A. Some people did. Not everybody.
Q. Okay. Was there any major change in the team?
A. There were some new people who were added to the team.
Q. Do you remember who those people were?
A. For example, on the marketing team, Matt Napoletano was added to the team.
Q. And what was his job description or what did he do?
A. He was a marketer.
Q. I see. Okay.
A. And then -- but he was a marketer for awhile, and then he was put on our other product, Amrix.
Q. Were you working on Amrix during this time as well or not?
A. Yes.
Q. At any rate, from a marketing perspective and a promotional perspective, though, is it your understanding that as far as the marketing strategies were concerned, those continued and just

were transferred over to Fentora?
MR. JAMES: Objection.
THE WITNESS: I'm not sure I understand the question.
BY MR. CARTMELL:
Q. Well, for example, during the Actiq time period. There had been, for example, key opinion leaders who had been hired as consultants by Cephalon to consult related to Actiq, for example; correct?
A. Yes.
Q. When Actiq was no longer being promoted by the company and Fentora now was on the market and took its place, were those same key opinion leaders then transferred to Fentora as consultants?
A. I don't know for sure. I suspect some were. I don't know if all of them were.
Q. Okay.
A. And I don't know if there were additional people involved as well.
Q. As far as the basic plan and strategy for marketing and promotion and PR, was there any change in that specifically, that you can recall?
MR. JAMES: Objection.

THE WITNESS: I -- the biggest change that I would suggest there was is from the very beginning, there was an intent to -- to do clinical trials.
BY MR. CARTMELL:
Q. Okay. And was that because, as we saw from your quote, the company's strategy with respect to Fentora was that even though the FDA had only approved it for cancer pain, breakthrough cancer pain, the strategy was that it would do clinical trials and then submit those to the FDA in noncancer conditions so that that could support a supplemental new drug application and expansion into other pain conditions?
A. Other breakthrough pain cancer conditions.
Q. Other breakthrough cancer conditions?
A. I'm sorry. Other breakthrough pain conditions.
Q. So it's clear for the jury, the plan from the very beginning with Fentora, I take it, was that studies would be done by key opinion leaders and, for example, back pain and neuro pain; correct?
A. These were major clinical trials. These were not Phase 4 trials. They were randomized placebo-controlled studies of the use of Fentora for

breakthrough pain in opioid-tolerant patients in different conditions. They were studies that were directed by the company, not individual investigators. And in part the clinical development plan was developed in recognition of the fact that there was use outside the label, and we understood that there was interest in the community and wanted to provide adequate data to be able to guide that usage.

(Exhibit No. 19 was marked.)

MR. CARTMELL: Okay. Let me hand you what's been marked as Exhibit 19, which I believe lists you as the media contact on a press release.

Q. Do you see this?

A. Yes.

Q. And this press release, I think it has a date, it's October 11th of 2006; is that right?

A. That's what it states, yes.

Q. And my understanding from the internal documents and the approval documents for Fentora, Fentora had only been on the market for a month at this time; is that consistent with your memory?

A. I don't remember the exact approval date, but that sounds approximately right.

Q. Okay. And as you stated, the company was doing studies or had been doing studies using this new product that had only been on the market at this time, I think for a month, in off-label conditions like back pain, and I think another one was in some type of neurological pain; correct?

A. Neuropathic pain, correct.

Q. And so this is a press release issued by the company. It states:

(Reading) Frazer, Pennsylvania, October 11, 2006: Cephalon today announced that data from a Phase 3 clinical trial of Fentora demonstrated efficacy in the management of breakthrough pain in opioid-tolerant patients with chronic low back pain (end of reading).

Right?

A. That's correct.

Q. So the company had done its own study; is that what you said?

A. Yes.

Q. In other words, they didn't hire consultants or key opinion leaders to do the study?

A. There were people who were brought in

as clinical investigators in the community, but we directed the development of the study.

Q. Okay. But you did pay clinical investigators -- I think like was Dr. Portenoy on one of the studies?

A. I don't know if Dr. Portenoy was on one. He was on our Actiq cancer-related breakthrough pain studies. I don't know -- recall if Dr. Portenoy was on one of these studies.

Q. Okay.

A. And with respect to payment, the payment, if there was any payment, was consistent with whatever our policy was at the time. Nothing unusual was done with these investigators as compared to any -- any investigators on any of our studies.

Q. Okay. At any rate, this is at a time in October, the product has just been on the market for a month, and the company has entered into a RiskMAP, Risk Management Program, as we have seen, where the company has told the FDA that it would not off-label market Fentora, and it was going to do everything it reasonably could to achieve its number one goal, which was to make sure that Fentora was used by cancer patients with breakthrough pain and who were opioid tolerant; correct?

MR. JAMES: Objection.

THE WITNESS: These studies were done for scientific purposes, and it doesn't -- it was -- they were ongoing because the decision was made, from a corporate perspective, to first submit the cancer data with the intent that we always were going to submit an SMDA depending on the outcome of the research.

MR. CARTMELL: I will move to strike that as not responsive to my question. Let me ask it again.

Q. This press release is at a time in October when Fentora had just come on the market for a month, and the company had entered into a RiskMAP or a Risk Management Program with the FDA, as we've seen, and had told the FDA that it would not off-label market Fentora, and it was going to do everything it reasonably could to achieve its number one goal, which was to make sure that Fentora was used by cancer patients only; correct?

MR. JAMES: Objection.

THE WITNESS: A randomized, placebo-controlled clinical trial is not promotional.

BY MR. CARTMELL:

Q. I'm not asking that. I'm really only asking you -- I'm asking specifically about what time

period this was and what the RiskMAP said, okay? So let me ask it again.

These studies were -- strike that.

The press release that we're looking at is at a time in October when Fentora had just come on the market for one month, and the company had entered into a RiskMAP or a Risk Management Program with the FDA, as we've seen, and the company had told the FDA that it would not off-label market Fentora, and it was going to do everything it reasonably could to achieve its number one goal, which was to make sure that Fentora was used by cancer patients only; correct?

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. I'm not asking about the actual studies. I'm just asking about that. And then we will talk about the press release.

MR. JAMES: Objection.

THE WITNESS: The -- the RiskMAP -- I think it was called a RiskMAP at that time -- was limited to cancer-related breakthrough pain.

BY MR. CARTMELL:

Q. Okay. And there was nothing in the RiskMAP that said anything like, if you did studies

on noncancer patients, that the company could use that data and promote those off-label uses; was there?

A. No, there was nothing in the RiskMAP to that extent, because risk maps are tied to an approved indication.

Q. Right. And so let's look at this press release that you have sent -- you have sent out. And were you the one responsible for putting this together?

A. Yes.

Q. Okay. And when you send out a press release like that -- like this, who do you send it to?

A. We -- we had a media distribution list.

Q. Okay. And that would be media outlets all over America?

A. It was major media outlets.

Q. Okay. Give us the names of some.

A. It would be, for example, the New York Times, the Wall Street Journal, you know, major -- major press, AP, Reuters, outlets of that nature.

Q. So the company is putting out in its

press release, sending it to the major press or media outlets, hoping that they pick that up and then they write an article in their media about this; correct?

A. That is correct.

Q. Okay. And so this states:

(Reading) Further data from the Cephalon-sponsored study will be presented at upcoming medical meetings, including a poster presentation at the American Society of Regional Anesthesia and Pain Medicine November 16th and 19th, 2006 in San Francisco (end of reading).

Right?

A. That's what it states.

Q. There's then a quote:

(Reading) The results of this study suggest that Fentora may have application beyond its current indication in cancer and provide important support to our strategy for future label expansion in breakthrough pain associated with multiple chronic pain conditions (end of reading).

Correct?

A. Yes.

Q. That's what it says?

A. And that's what I -- yes, that's what I just said.

Q. Right. So this -- the intent of this press release, though, is that it is seen by patients and physicians out in the public, and that they then learn this information that possibly Fentora can be used for back pain; correct?

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. That's the intent?

MR. JAMES: Objection.

THE WITNESS: The intent is for the public to know that there's been a clinical trial, and there are data that is going to be presented at a future medical meeting.

BY MR. CARTMELL:

Q. But this is a promotional activity; correct?

MR. JAMES: Objection.

THE WITNESS: It is primarily an investor relations activity, not a promotional activity, because this information was material to our

business, and, therefore, it needed to be communicated to the investor community that we had completed a major clinical trial.
BY MR. CARTMELL:
Q. Because the idea being that if an investor community sees this, your stock price might go up; correct?
A. No. It's a matter of disclosure.
Q. Well, this is in part a promotional activity as well; correct?
MR. JAMES: Objection.
THE WITNESS: I would not -- promotional activities are intended, in my opinion, to be direct contact, as we talked before, with a clinician who can prescribe. This is an indirect -- one could say this is an indirect educational outreach, but it is not direct promotional pieces, and it's guided by FDA. And as you can see, we included all the important safety warnings in this press release as appropriate.
BY MR. CARTMELL:
Q. Okay. The bottom line is, the product has only been approved for cancer pain -- and this is a press release that's sent all over America saying that there are results now that possibly

allows Fentora to be used for back pain; correct?
MR. JAMES: Objection.
THE WITNESS: That's correct.
BY MR. CARTMELL:
Q. And this is within a matter of months that the company has committed to the FDA that its number one goal is to try to ensure that the product will only be used in patients who have cancer pain; correct?
MR. JAMES: Objection.
THE WITNESS: Participation in clinical trial is different than promotion.
MR. CARTMELL: I will object and move to strike that.
Q. My question is a little different than that. Mine is -- the question is on timing. My question is: And this is within a matter of months that the company has committed to the FDA that its number one goal is to try to ensure that the product will only be used in patients who have cancer pain; correct?
MR. JAMES: Objection.
THE WITNESS: This study was begun before then.
///

BY MR. CARTMELL:
Q. Okay. I'm not asking about the study. I'm asking about the press release. So I will move to strike that.
My question only has to do with the timing of this. I will ask it one more time.
My question is this: This is within a matter of months that the company has committed to the FDA that its number one goal is to try to ensure that the product will only be used in patients who have cancer pain; correct?
MR. JAMES: Objection.
THE WITNESS: The intent of --
BY MR. CARTMELL:
Q. I'm not asking about the intent. I don't mean to -- I'm not asking about the intent.
A. I am answering your question.
Q. You're really not.
A. This is shortly after the Risk Management Program, RiskMAP, was put in place to talk about opioid-tolerant use in cancer patients.
Q. Okay. I cut you off, so I want to get a clean question and answer.
My question is that this is within a matter of months, this press release, that the company has

committed to the FDA that its number one goal is to try to ensure that the product will only be used in patients who have cancer pain; is that correct?
MR. JAMES: Objection.
THE WITNESS: It's correct in terms of timing.
(Exhibit No. 20 was marked.)
BY MR. CARTMELL:
Q. I'm going to hand you an Exhibit 20. Sorry. This is a big one. I think that's two. Is that two?
A. It doesn't have a number on it.
MR. CARTMELL: Oh, here you go. Sorry. It's on my finger.
Q. This is a PowerPoint presentation that came from the internal files and were produced in this litigation. It's titled, "FAST Team meeting, January 18th, 2007." And I believe this was in your custodial file. Do you recognize this?
A. I'm sure that I have seen it before. I don't directly recognize it.
Q. Okay. The FAST Team, I take it, means Fentora assessment strategy tactics; correct?
A. Yes.
Q. And the FAST Team was involved in

promotional and marketing strategies as well as public relations; is that correct?

A. It was a cross-functional team.

Q. Including public --

A. Including marketing.

Q. Okay. Sorry.

A. Including marketing.

Q. And if you go to -- I don't think these -- maybe there is page numbers. Mine doesn't have it. Is there another one? Oh, here's one.

I'm looking at the page that's entitled, "PR Update." Ms. Beckhardt, if you would turn to page 68. I believe it states -- okay. Okay.

If you turn to page 68, there's PR update. Do you see that?

A. Yes.

Q. And 69 has some things, I take it, that you and your team or you were presenting; is that correct?

A. Yes.

Q. One of the things that you were doing related to Fentora at this time was a breakthrough pain awareness campaign; is that right?

A. A disease-specific nonproduct-related campaign, yes.

Q. Right. And we talked about this. But this is a campaign where you were trying to increase the awareness of what's called breakthrough pain; correct?

A. That is correct.

Q. And not -- not just cancer breakthrough pain, but you were talking about increasing the awareness of breakthrough pain in even back pain -- or the cause being back pain or other disease processes causing the breakthrough pain; correct?

A. As we were doing clinical trials in those other areas, yes.

Q. Right. And so part of the things that you wanted to do is get your messaging out there about the awareness of this disease process or condition called breakthrough pain; correct?

A. Because there was very -- it was very poorly recognized and undertreated at the time.

Q. Right. And so there were some patients, right, who had cancer breakthrough pain; right?

A. Absolutely.

Q. And that number of patients, as we saw, would be a lot smaller than the number of

patients that had, for example, breakthrough pain caused by back pain, for instance; correct?

MR. JAMES: Objection.

THE WITNESS: The number of patients who were opioid tolerant were -- there were additional, but I don't think it was that much larger than the actual cancer pain population, if you looked at those patients who were already on opioids around the clock.

BY MR. CARTMELL:

Q. Okay. But -- but -- and then there was other disease states, several others that you were trying to get this information out to breakthrough pain, but their cause was not cancer; correct?

A. That's correct.

Q. And the hopes was -- or the hopes were, for the company, I take it, that these individuals who had breakthrough pain that was not caused by cancer would also be interested in possibly being prescribed your product Fentora; correct?

MR. JAMES: Objection.

THE WITNESS: I didn't speak about the specific products.

MR. CARTMELL: I understand.

THE WITNESS: I did disease awareness.

BY MR. CARTMELL:

Q. But -- but the only reason that your company would be interested in reaching back pain patients who are on opioids and neuropathic patients who are on opioids and headache and migraine patients who are on opioids, the only reason your company would want to educate them on back -- on breakthrough pain would be if they were potential candidates for your breakthrough pain cancer medication; correct?

MR. JAMES: Objection.

THE WITNESS: The interest in doing disease state of education did correspond with the intent to do a supplemental NDA.

MR. CARTMELL: Right.

THE WITNESS: Which was to expand the indication beyond cancer.

BY MR. CARTMELL:

Q. Right. And you're doing all of this breakthrough pain awareness at a time when the product Fentora did not have an indication and had never been at that point found to be safe and effective in anything other than breakthrough cancer pain; correct? That's a timing question.

A. What is the timing of this?

Q. This is 2007.
A. Well, this particular plan is after the data on low back pain were completed.
Q. Yeah, but --
A. After that study was completed, in which we had evidence that suggested that the product was safe and effective in that population. It had not been reviewed by the FDA, but we had the clinical trial completed.
Q. That's the point, isn't it? The FDA had not reviewed the data to tell you that it was safe and effective for breakthrough pain in back pain patients, had it?
A. The FDA had not yet. We had not submitted the application.
Q. But your company decided that you could send out press releases all over America and do breakthrough pain awareness campaigns without the indication at that time, because the FDA hadn't even seen the data; correct?
MR. JAMES: Objection.
THE WITNESS: Sending out a press release --
BY MR. CARTMELL:
Q. First of all, you can answer it, and then explain it. Is that correct?

MR. JAMES: Objection.
THE WITNESS: We sent out materials before the approved indication, yes. But sending out a press release is not a direct promotion to health-care providers who can prescribe the medication. And it is consistent with the need under the FCC to share material information.
BY MR. CARTMELL:
Q. Do you know if it's consistent with the RiskMAP that obligated the company not to off-label market or promote the product for anything other than cancer pain? Is it consistent with that?
A. These were clinical trials.
Q. My question is not if it's a clinical trial.
A. Then I -- I understand that, but I do not believe clinical trials are inconsistent with the RiskMAP.
Q. Okay. Does the RiskMAP mention anything that allowed the company to actually promote or market clinical trials in off-label indications? Does it mention anything?
A. It does not mention that.
Q. Okay. If you turn to page 70 --
A. Yes.

Q. -- this is talking about early Fentora approval coverage. And this is a quote that came from a press release that you put out after Fentora was approved in 2006; correct?
A. That is correct.
Q. And at that time you actually included a quote from your CEO; is that correct?
A. That's correct.
Q. Frank Baldino?
A. Yes.
Q. And the quote was:
(Reading) Longer-term clinical strategy is focused on developing Fentora for patients with breakthrough pain associated with other conditions, including neuropathic pain and back pain (end of reading).
Do you see that?
A. Yes, that's correct.
Q. This is a timing question, Ms. Beckhardt. But the timing of this statement by your CEO that was put in all of these media outlets and stories were run all around the nation, the timing of this quote was within a matter of months of the company telling the FDA in the RiskMAP that it

would do everything possible to meet its number one goal which was to ensure that this product was only used in cancer patients; correct?
MR. JAMES: Objection.
THE WITNESS: If you're talking timing, this press release was issued not too far after the product was approved for breakthrough cancer pain.
BY MR. CARTMELL:
Q. Okay. I want to ask you a question about page 74, if you don't mind. "Radio Media Tour; Chronic Low Back Pain Study." Do you see that?
A. Yes.
Q. Now, John Peppin, DO, who is pictured here; is that right?
A. Yes.
Q. He was one of the investigators in the low back pain study with Fentora; is that correct?
A. That's correct.
Q. And he was one of the authors on the publication; is that right?
A. To the best of my memory.
Q. And that publication, incidentally, also included I think Mr. Messina, who is an employee inside of Cephalon; is that correct?

A. Yes. He was the head of our clinical development program for Fentora.
Q. Okay. Okay. And this Dr. Peppin was a key opinion leader for the company and was a paid consultant for the company?
A. I believe that he did receive payment for some of his activities.
Q. Okay. And so Mr. Peppin, according to your update on public relations media activities going on with Fentora, did interviews around December 19th, around Christmas, with an audience reach of 3.5 million people to talk about the results of the Fentora study with chronic low back pain; is that correct?
A. That's correct.
Q. And this is a timing question, Ms. Beckhardt. But this was in a matter of months that the company had agreed with the FDA that it would try to achieve and ensure as its number one goal that Fentora was only used in cancer patients; correct?
MR. JAMES: Objection.
THE WITNESS: That it is within a few months that we did this radio -- of the approval that we did the radio media tour.

BY MR. CARTMELL:
Q. And if you look at page 75, it talks about some of the messages that were conveyed by Dr. Peppin; do you see that?
A. Yes.
Q. And when you talk about messages, these were messages -- actually, we've talked about that term "messages" that the company wanted Dr. Peppin to convey in his radio tour; correct?
A. These were messages that we discussed with Dr. Peppin to make sure that he agreed that they were medically accurate based on the data that we had in our clinical trials.
Q. Well, he's a doctor; right?
A. That's right.
Q. He can determine that?
A. That's right.
Q. But at any rate, what he did in this radio media tour that reached 3.5 million people around the country was talk about the use -- what he did in part was talk about the use of Fentora in an off-label condition for back pain; correct?
A. He discussed it in the context of a clinical trial.
Q. Okay.

(Exhibit No. 21 was marked.)
BY MR. CARTMELL:
Q. Let me hand you Exhibit 21, which is another FAST Team meeting PowerPoint six months later. If you go to the first page of the PowerPoint, you will see this is FAST Team meeting July 20th, 2007. Do you see that?
A. Yes.
Q. Now the product has been on the market for a little less than a year. But if you -- if you turn to the back -- actually, the last three digits of the -- oh, excuse me, Ms. Beckhardt, if you turn to page -44, please.
MR. JAMES: Bates label -44?
MR. CARTMELL: Yes.
THE WITNESS: This, okay.
BY MR. CARTMELL:
Q. This is a slide that's an overview of what the company is planning in 2008; is that correct, for Fentora?
A. This looks to be -- these are presentations of clinical data based on different studies at various medical meetings.
Q. Okay. So, again, several of these studies deal with off-label usage like back pain and

neurologic pain; is that correct?
A. I don't know that for certain. But I would imagine given the timing, that's correct.
Q. Okay. And -- and one of the things that Cephalon would do as a part of its strategy related to Fentora was these studies that had been done by the company on things other than cancer pain would be presented by doctors at national meetings that involved doctors; is that right?
A. That's standard practice for clinical data to be disseminated at a medical meeting.
Q. Well, it was standard practice of Cephalon --
A. It's standard practice in every pharmaceutical company, and every -- that I'm aware of to release data at a medical meeting where physicians have and other health-care professionals are in an environment where they can do scientific exchange. It is not considered promotional by the FDA.
Q. Is it your belief that it's standard practice to do this for off-label uses?
A. When you're doing additional --
Q. First, can you answer that question?
A. Do I think it's standard practice?

Q. Let me ask it again. I didn't mean to cut you off. But I just -- if you could answer that question so we can move things along.

Is it your testimony that it's standard practice at national meetings for doctors to present data related to pharmaceutical medications in off-label studies?

A. Yes.

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. Okay. And if you -- if you look down here, it talks about the presentations at these meetings are going to be about breakthrough pain, and part of the message is going to be -- marketing message is going to be that there are similar characteristics in cancer and noncancer breakthrough pain; correct?

A. I think you're misinterpreting what this says.

Q. Okay. Let me -- let me ask you, though. Does the first bullet point say, "Breakthrough pain, similar characteristics in cancer and noncancer"?

A. That was based on clinical data, yes, that is what it says.

Q. Okay. And I -- I don't think I've asked you this. But at this time, it's true, is it not, that Fentora was the only breakthrough cancer pain medication on the market?

A. That's not true because Actiq was on the market.

Q. Okay. That's a good point. I apologize.

Is it true, then, that the only breakthrough cancer pain medications on the market at this time were Actiq and Fentora?

A. That's correct.

Q. Okay. And is it true also that the only medications at this time that had a breakthrough pain indication of any kind on the market were Actiq and Fentora?

A. That is correct.

Q. So it's true that if you were doing breakthrough pain awareness messaging around America to doctors and patients, and things like that, the only medication that any pharmaceutical company had with that indication was Cephalon; correct?

A. That is correct.

Q. So it's true that you wanted to include awareness of breakthrough pain because you

guys had the only drugs that had any indication of breakthrough pain, albeit, it was only for cancer; correct?

MR. JAMES: Objection.

THE WITNESS: We were attempting to do a clinical development plan because we recognized that there was clinical interest in using Actiq and Fentora outside of the approved indication. And our clinical development plan was designed specifically to address some of the issues we saw with Actiq where usage was outside the label.

BY MR. CARTMELL:

Q. Right.

A. And that's why from the beginning of the development we were very clear of our intent to study this outside of cancer so that we could have, in our mind, appropriate information on the label because that's -- because those usages in those patient populations there was breakthrough pain.

Q. But -- but what your company chose to do is not just do the studies, your company decided to have a strategy that those studies would be -- the results for those studies for off-label uses would be shot out in press releases all over America, for one; correct?

MR. JAMES: Objection.

THE WITNESS: You're making it sound like there's something wrong with that.

BY MR. CARTMELL:

Q. I'm just asking if that's factually correct.

A. It is correct that we issued press releases.

Q. The other thing you did is you didn't just do those studies and give them to the FDA so that they could decide whether or not it was safe to have Actiq or Fentora used for back pain and other things, is you decided to have key opinion leaders go around America and present those studies to other doctors before it was indicated; correct?

A. We had -- we had data presented at medical meetings by physicians.

Q. And all of that was done at a time when you knew the FDA was extremely concerned about abuse and misuse and diversion of Fentora because of the extreme off-label use that had happened with Actiq; correct?

MR. JAMES: Objection.

THE WITNESS: I don't know that that is what FDA's motivation was.

BY MR. CARTMELL:

Q. Okay. Well, it was all done at a time when the FDA had required you, your company Cephalon, to enter into a Risk Management Program with Fentora; correct?

A. That is correct.

Q. And your company was the only opioid company in America that had a Risk Management Program associated with its drug at that time; correct?

A. That is correct.

Q. And not only that, you decided also -- strike that.

Let's turn to page 72, medical center briefings. This is a slide that talks about presentations that were given around America titled, "Managing Pain: Improving Patient Outcomes and Minimizing Risks in Opioid Therapy of Chronic Pain."

Do you see that?

A. Yes.

Q. Now, Fentora was not approved by the FDA for use in chronic pain; correct?

A. It was approved for use in breakthrough cancer pain, which is a component of chronic pain.

Q. But you could not promote at this

time -- in other words, a sales rep couldn't go into a doctor's office and promote the use of Fentora for chronic pain; correct?

A. We never intended to promote it for chronic pain.

Q. Because that would be illegal off-label promotion; correct?

MR. JAMES: Objection.

THE WITNESS: The product was approved for breakthrough pain, and we never intended it for -- for it to be a substitute for the products that were used to treat chronic -- the baseline medicines to treat chronic pain.

BY MR. CARTMELL:

Q. Ms. Beckhardt, this slide includes the names of several doctors who were giving presentations around America about managing chronic pain; correct?

A. That is correct.

Q. And these presentations were supported and sponsored by Cephalon; correct?

A. That is correct. They were put together by an independent organ- -- CME company. But we did sponsor the presentations.

Q. And these individual doctors were

paid grants or consulting fees to do that for the company; correct?

A. They were not paid by Cephalon. They were selected by the CME company.

Q. So Cephalon would pay the CME company, and then the CME company may pay them; correct?

A. But we did not select the speaker. We do -- in the CME program, the company does not select the speakers.

Q. But you understood -- just so it's clear to the jury, you understood that you would make a payment to the CME company, and the CME company would then pay the doctor for the time; correct?

A. An honorarium. But we did not select who those physicians were.

Q. Let's talk about those physicians. Scott Fishman was a key opinion leader, a paid consultant of your company; wasn't he?

A. For a short period of time.

Q. So was Steven Passik; correct?

A. Yes.

Q. So was Gerald Aronoff; correct?

A. Correct.

Q. So was Howard Heit; correct?

A. Yes.

Q. So was Perry Fine; correct?

A. Yes.

Q. Every one of these people were paid consultants of your company who were going around America and talking about the use of Fentora in off-label indications; correct?

A. All of these individuals are key opinion leaders and major, major names within the pain community.

Q. Your company would make sure, right, that they were choosing as their key opinion leaders people who were respected in the community; correct?

A. That is correct. But some of these people -- for example, Scott Fishman -- was not -- was not a prescriber of Actiq or Fentora, to the best of my knowledge. So these are not people who were selected based on their prescribing practices. They were selected from the CME company and ourselves based on their expertise in pain medicine.

Q. And also on whether or not they believed in the prescribing of fentanyl-based products for breakthrough pain; correct?

A. These physicians did believe in the prescribing of fentanyl breakthrough pain products

for breakthrough pain.
MR. JAMES: Let's take a break, a quick break. We have been going for awhile.
THE VIDEOGRAPHER: We are going off the record. The time is 5:29 p m.
(Recess taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 5:38 p m.
BY MR. CARTMELL:
Q. Ms. Beckhardt, we are back on the record after a short break. Are you ready to proceed?
A. Yes.
Q. Now, we were talking about or had been talking about the company's promotion and marketing and PR tactics related to Fentora; do you recall that?
A. Yes.
Q. And in 2008, as we've discussed, the company -- or prior to 2008 submitted some studies on back pain and neuropathic pain to the FDA and asked the FDA to determine whether or not it would allow Cephalon to have an indication and find that it was safe and effective for the company to promote and market and sell Fentora for breakthrough pain in

other noncancer conditions; correct?
A. That is correct.
Q. And the answer from the FDA was that they did not believe -- although it was efficacious, meaning that the pain therapy worked, they did not believe that it could be indicated because of concerns related to abuse and misuse and diversion; correct?
A. I don't remember the exact language, but I'd have to look at the exact language that FDA used.
Q. At any rate, you recall that the FDA declined the company's application for a broader --
A. That is correct.
Q. -- indication?
A. That is correct.
Q. So even though Cephalon, for a period of time, had been sending out press releases about using Fentora in back pain for two years, and even though Cephalon had been hiring doctors who were talking about studies and back pain and neuropathic pain with Fentora for a period of time, when the FDA was asked if it was safe and effective to approve Fentora for that reason, the FDA said no; correct?
MR. JAMES: Objection.

THE WITNESS: The FDA declined our application for an sNDA; that is correct.
BY MR. CARTMELL:
Q. But by the time that the FDA made that determination, it had the ability to review the data, it's true, is it not, that Fentora already had an extreme off-label usage; correct?
MR. JAMES: Objection.
THE WITNESS: I don't know how to characterize something as extreme.
BY MR. CARTMELL:
Q. Well, eight out of ten patients who were on Fentora were not on it for the indicated cancer pain use; correct?
A. I don't remember the exact statistics, but that's probably about right.
Q. Okay. And I think we saw a document that with Actiq, it was nine out of ten patients that were on Actiq for a reason other than cancer pain; correct?
A. That's probably about right. And that's why we undertook the clinical development program --
Q. So --
A. -- where the uses were shown to be

efficacious.
Q. But isn't it important to you that even though the pain medicine worked, in other words, these are extremely potent pain meds, and what you're saying is they work, right? They help the pain for people with back pain; right?
A. That's correct.
Q. But what the FDA was saying, remember, the FDA was saying, but we don't think it should be expanded to back pain and arthritis and headaches because that's going to make it so available that there's going to be more abuse and misuse and diversion; right?
MR. JAMES: Objection.
THE WITNESS: I -- I can't say what the FDA was thinking.
BY MR. CARTMELL:
Q. Okay. Well, let's look, because we looked at this earlier, at Exhibit 9. The first page of the Director of the Division of Anesthesia, Analgesia and Rheumatology Products memo in April of 2008; remember? If we look down at the sentence:
(Reading) These Risk Management Plans were designed to limit the prescribing of these products to opioid-tolerant

patients with breakthrough pain from cancer, with the intent that this would limit the overall prescribing of the medication and perhaps limit the amount of diversion for abuse and the number of -- perhaps limit the amount of diversion for abuse and the number of accidental exposures (end of reading).

See that?

A. Yes, I see that. I can read that.

Q. Okay. And that's what we talked about earlier, that the whole concern of the FDA was they wanted to keep this limited to cancer patients. That's what this says; right?

MR. JAMES: Objection.

THE WITNESS: That is what it says. And the concern includes the word "perhaps."

BY MR. CARTMELL:

Q. Right.

A. It was a theoretical concern.

Q. Well, it wasn't, because let's read the next sentence:

(Reading) However, off-label prescribing has unfortunately been

widely practiced. In the short time that Fentora has been on the market and despite a limited indication for cancer patients, we have received numerous reports -- numerous reports of serious adverse events related to the product, including deaths in patients, prescribing to nonopioid-tolerant patients, misunderstanding of dosing instructions and inappropriate substitutions of Fentora by pharmacists and prescribers (end of reading).

It wasn't just perhaps. They had experience with it. They had actual adverse events, including deaths; correct?

A. That --

Q. Ms. Beckhardt, is that correct?

A. That is correct. However, it is one of the reasons we wanted to do these studies, so we could get the data related to these other indications into the label so there could be a better understanding of that usage within those populations.

Q. But that could just -- what the FDA

was telling you, is that would just increase the numbers even more?

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. Would be more widely used, that's what they told the company; right?

MR. JAMES: Objection.

THE WITNESS: That's what FDA said. I don't know if I concur with that statement.

BY MR. CARTMELL:

Q. The agency issued a public health advisory regarding Fentora last September:

(Reading) Additionally, we worked with Cephalon, the sponsor, to make a number of modifications to strengthen the warnings in the product label (end of reading).

Do you see that?

A. That's correct.

Q. And then it says in the next paragraph in the middle:

(Reading) We are concerned that the sponsor's request to expand the current indication for Fentora to opioid-tolerant patients with

breakthrough pain who do not have cancer may greatly increase the prescribing of this product, which may increase the availability of the product for diversion, abuse, and misuse, and increase the incidence of accidental exposures which, due to the potency of the product, could potentially have devastating effects (end of reading).

Do you see that?

A. I see that statement.

Q. And then it says:

(Reading) In this time of increasing abuse of prescription opioid products, it's important to address this potential and to find effective risk mitigation strategies to intervene before it manifests as a public health crisis (end of reading).

Do you see that?

A. I see that statement. But we --

Q. And this was back in 2008; wasn't it?

A. Yes. But we were a very small part of the market.

Q. So you were a very small part of the abuse and misuse and diversion that led to the opioid crisis?

MR. JAMES: Objection.

THE WITNESS: We saw very low levels of abuse and diversion in our products.

BY MR. CARTMELL:

Q. That's -- but remember, we talked about this. You only know what was reported to the company, don't you?

MR. JAMES: Objection.

THE WITNESS: We had no other evidence. We did not see any consistent patterns in any geographic areas. We had no -- we had no information that would suggest that we had a major problem with abuse and diversion.

BY MR. CARTMELL:

Q. That's not what the FDA is saying. They said they had increasing reports of serious adverse events; didn't they?

MR. JAMES: Objection.

THE WITNESS: Those aren't -- that is not related to diversion. Serious adverse events relate to patients who got those products.

///

BY MR. CARTMELL:

Q. Let's look at what you just said and determine if that's what the FDA's experience was.

Look at, if you would, the last three Bates stamped digits -415. Wait, that's not going to help you. -4415.

This is actually a memo from a committee within the FDA that was asked to look specifically at whether Cephalon was doing the things they were asked to do in the Fentora Risk Management Program; correct?

A. I have to look at this, please.

Q. Sure. Are you at that page? I don't think you are.

A. I'm at -415. -4415 at the end.

Q. Okay. Good.

A. Yes, that appears to be an FDA meeting to that effect.

Q. And in the subject -- well, this was a committee that was put together specifically to look at, for the FDA, the Fentora Risk Minimization Action Plan and the post-marketing experience related to that; do you see that?

A. That's correct.

Q. If you go to actually page 2 of that,

which is -4418, there's an Executive Summary. Do you see that?

A. Yes.

Q. This committee gave an Executive Summary to Cephalon, and this is what it says:

(Reading) The memorandum provides the office of surveillance and epidemiologies preliminary assessment of the performance of the approved Fentora Risk Minimization Action Plan in meeting its risk minimization goals as well as a review of the overall post-marketing experience with Fentora to date (end of reading).

Do you see that?

A. Yes.

Q. So the FDA has actually done -- put together a committee and actually done investigation and looked at, among other things, whether or not your company was doing its job with respect to the risk management plan; correct?

MR. JAMES: Objection.

THE WITNESS: It was looking at the -- whether the Risk Management Program was working.

///

BY MR. CARTMELL:

Q. Right. And it also was looking at the post-marketing experience, meaning were there increasing abuse, misuse, diversion, those types of things; right?

MR. JAMES: Objection.

THE WITNESS: Post-marketing experience just means once the product is on the market.

BY MR. CARTMELL:

Q. Right. So what this committee was looking at is after Fentora was on the market and your Risk Management Program was in effect, were you doing your job to try to decrease misuse, abuse, diversion, addiction, things like that? That's what this committee was looking at; right?

MR. JAMES: Objection.

THE WITNESS: I think the company was looking at the effectiveness of the RiskMAP, which is not just about what a company does but whether the way the RiskMAP was structured was effective.

BY MR. CARTMELL:

Q. Well, let's -- let's -- let's look at that. But before we look at that, isn't it true that Cephalon put together that Risk Management Program?

A. In conjunction with the FDA. And in

truth, as we moved forward for the RMS that we proposed with the expanded indication, we actually proposed things that were more -- that included more provisions than the FDA put into the ultimate turf RMS.

Q. The ultimate turf RMS that you're talking about was a more strict, much more strict program?

A. I understand. What we proposed for the SNDA was stricter than that.

Q. There wasn't a very strict RMS program put into place until 2012; correct?

MR. JAMES: Objection.

THE WITNESS: I understand what we proposed.

BY MR. CARTMELL:

Q. I'm just asking for the timing of it.

A. That's correct.

Q. There wasn't a strict RMS program that was really prohibitive related to the use of Fentora put into place until 2012; correct?

A. That's probably about the right timing.

Q. And you had already left the company by then, I think; correct?

A. Yes. I probably just had left.

Q. All right. And the FDA required you to do a much more intense and restrictive program, Risk Management Program, related to Fentora, didn't it?

A. Not just Fentora. All products in the class.

Q. Okay. Let's go and look what they found, this committee that looked at what Cephalon did with Fentora's RiskMAP and how -- how they were doing as far as safety.

It states:

(Reading) A RiskMAP was approved at the time of the initial FDA approval. Fentora as an important part of its post-marketing risk management to: One, minimize the use of Fentora by opioid nontolerant individuals, minimize misuse of Fentora, and minimize unintended accidental exposures (end of reading).

Do you see that?

A. Yes.

Q. If you go down to the next paragraph, it states:

(Reading) Fentora use has increased

more than fivefold since the initial first quarter launch in December 2006 with most use occurring off label in noncancer pain indications, and a significant amount of use occurring in opioid-nontolerant individuals (end of reading).

Do you see that?

A. I see that it states that.

Q. And that was another requirement of the risk mapping. In fact, you had continually referred me to that requirement, that one of the biggest concerns with this Fentora drug was it had to be given to opioid-tolerant patients or else it could be very dangerous; correct? Is that correct?

A. That is correct.

Q. Okay. And, in fact, the FDA found that in 2007, approximately 59 percent of the patients who filled a prescription for Fentora were on concurrent therapy with a product from the pain market; correct? Do you see that?

A. That actually suggests that they were opioid tolerant if they were on concurrent therapy.

Q. Okay. And exactly that's my point. Only 59 percent, meaning 41 percent of the patients

in 2007 who took Fentora, the FDA found were not opioid tolerant; correct?

MR. JAMES: Objection.

THE WITNESS: According to these statistics.

BY MR. CARTMELL:

Q. Four out of ten patients who took the drug were not opioid tolerant, according to these prescriptions, even though the company had told the FDA that it would do everything reasonable in its power to ensure its goal that the patients who took Fentora would be opioid tolerant; correct?

MR. JAMES: Objection.

THE WITNESS: My --

BY MR. CARTMELL:

Q. Is that correct?

A. That is correct. However, I will say that in my -- to my knowledge, I don't believe there were any materials coming out of the company that did not stress opioid tolerance.

Q. Regardless, we know, according to what the FDA found, the program wasn't working because four out of ten patients that were put on that drug were not opioid tolerant; correct?

MR. JAMES: Objection.

THE WITNESS: That's what this statistic

says.
BY MR. CARTMELL:
Q. It states:
(Reading) The majority of these adverse events occurred when patients were being treated for off-label uses for Fentora, such as back pain, chronic noncancer pain, and migraines (end of reading).
Do you see that?
A. I don't see where you are.
Q. Actually, the sentence before:
(Reading) Improper use in medication errors account for more than two-thirds of the adverse events reported with Fentora. The majority of these adverse events occurred when patients were being treated for off-label uses for Fentora, such as back pain, chronic noncancer pain, and migraines (end of reading).
Do you see that?
A. Yes.
Q. If you go to the next paragraph -- and I want to really stress this, make sure the jury

understands this:
(Reading) Based on this FDA committee's review: Based on our review of the post-marketing experience with Fentora, we do not believe the RiskMAP has been effective in minimizing the risks it was developed and implemented to minimize. Cephalon states in their approved RiskMAP that, quote, interventions will be instituted as warranted as follow-up to surveillance and monitoring activities. But they have never submitted information that interventions and/or adjustments were proactively considered or instituted to address RiskMAP goal failures, in particular, for the failure of the RiskMAP goal number one, that Fentora should be used only by opioid-tolerant patients with cancer (end of reading).
Do you see that?
A. I see what it says, yes.
Q. The same concerns and problems that happened with the Actiq RiskMAP, that huge rates of

off-label usage with Fentora just like Actiq; correct?
MR. JAMES: Objection.
THE WITNESS: It was used outside the approved indication.
BY MR. CARTMELL:
Q. (Reading) Fentora -- the number one goal that Fentora should be used only on opioid-tolerant patients with cancer, a goal that has consistently failed since the launch of Fentora. Instead, Cephalon uses the large extent of product off-label use, which reflects the failure of the RiskMAP goal No. 1, to justify the proposed expanded indication for Fentora (end of reading).
Do you see that?
A. Yes.
Q. And that's just what you did to this jury, what you said. You said you were justifying looking for an expanded use for the indication for Fentora because of this huge off-label Fentora use; weren't you?
MR. JAMES: Objection.

THE WITNESS: There was off-label use of the product. We recognized there was off-label use of the product. And we felt that it was appropriate to have data to support that use and to assess the safety in those patient populations.
BY MR. CARTMELL:
Q. And that's what the FDA committee that was put together by the FDA said was inappropriate, to justify the off-label use, or the subsequent -- strike that.
That's just what the FDA is talking about, the company was trying to justify getting an indication expanded just because it had a huge off label already; right?
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. That's what the FDA said?
MR. JAMES: Objection.
THE WITNESS: That is what it states.
BY MR. CARTMELL:
Q. It states:
(Reading) Expanding the Fentora indication as proposed will most likely amplify and exacerbate the adverse event trends and use pattern,

including use in opioid-nontolerant individuals we have already observed (end of reading).

So the FDA is telling the company, this committee is saying, we've already observed expanding trends here of adverse events with Fentora; correct?

MR. JAMES: Objection.

THE WITNESS: It speculates that expanding the education may exacerbate trends that they see.

BY MR. CARTMELL:

Q. Right. My point is simply they are already, as of 2008, seeing expanding adverse event trends with Fentora; correct? That's what it says?

A. I do not recall the date --

Q. I'm just asking if that's what it says.

A. That's what it says. But I do not recall the date. And I'd like to review something to see the date of this document relevant -- relative to another document.

Q. That's fine. Go right ahead.

A. Okay. Thank you.

Q. Ms. Beckhardt, I'm about done. And I want to ask you, did you or anybody at the company ever do any research into or look into how many

additional cases of addiction or misuse or abuse or overdose deaths, those sorts of things, there were with Actiq or Fentora because of the very high rates of off-label use?

A. Our pharmacovigilance team was responsible for looking at rates of adverse events, including diversion.

Q. Did you do any investigation, I guess my question is, outside the company -- not the reports just to the company -- to do any investigation to see how many additional deaths there were related to Actiq or Fentora because of the huge 80 and 90 percent off-label use with Actiq and Fentora?

MR. JAMES: Objection.

BY MR. CARTMELL:

Q. Did you do that?

A. I have a memory that we did get some information from some of the additional data sets that were not created by the company.

Q. What were those?

A. I don't remember the names of them.

Q. Where would I go to look for those?

MR. JAMES: Objection.

THE WITNESS: Where would you go to look for?

BY MR. CARTMELL:

Q. That data that you're talking about the company got.

A. I can't remember the names of the data sets, so I can't answer that question.

Q. Looking back in retrospect, Ms. Beckhardt, we talked about your suspicions and concerns related to the off-label marketing in the Marketing Department at the company; correct?

A. I had some concerns about some of the approaches that were taken, yes.

Q. And you mentioned that you talked to your superior about that; correct?

A. These were concerns when we were marketing Actiq, and it was before we initiated the clinical trials for Fentora.

Q. Ultimately, Fentora, after not receiving an expanded indication from the FDA, the FDA, as we talked, made or required -- not just Cephalon but other companies in America who were selling opioids to have a RMS, a Risk Management Program, put in place; correct?

A. For the transmucosal immediate release fentanyl products, yes.

Q. And were you involved in instituting that process?

A. No, I was not. I was involved in early discussions that we were having that ultimately led to some recommendations of making the RMS more stringent that came from Cephalon to the FDA.

Q. Okay. Cephalon and Teva stopped marketing Fentora; is that correct?

A. I don't know.

MR. CARTMELL: I think that's all the questions I have right now. Thank you very much for your time.

THE WITNESS: Thank you.

MR. CRAWFORD: I have some.

MR. JAMES: Okay.

MR. CRAWFORD: Could we go off the record for a second, stop the clock.

THE VIDEOGRAPHER: We are going off the record. The time is 6:03 p.m.

(Off the record.)

THE VIDEOGRAPHER: We are back on the record. The time is 6:04 p.m.

EXAMINATION

BY MR. CRAWFORD:

Q. Good evening. I think we just passed

the six o'clock point. My name is Mark Crawford, I represent the plaintiffs, and I'm going to have a few follow-up questions.

I want to hand you Exhibit 22.

(Exhibit No. 22 was marked.)

BY MR. CRAWFORD:

Q. And this is -- appears to be, just looking down, an email from you to a number of people, Matthew Napoletano, Denise Connelly and others, dated February 3rd, 2006. And this appears to be attaching some kind of budget for Cooney/Waters Group; correct?

A. That's correct.

Q. And were they a PR firm that Cephalon had hired to help them promote Fentora?

A. They were a PR agency that we hired to help do public relation strategies.

Q. All right. And were they hired -- did, in fact, you hire them or did Cephalon hire them about this time for Fentora?

A. They were working with the company prior to Fentora.

Q. All right. So for Actiq, they had helped with Actiq as well?

A. That's correct.

Q. And this is a budget for the launch of Fentora; correct?

A. May I take a minute to look at this, please?

Q. Yes.

A. It is -- it appears to be a proposal for the Fentora launch as well as other activities, yes.

Q. And was Cooney -- is it Cooney/Waters?

A. Yes.

Q. And were they retained by Cephalon at the time?

A. Yes, they were.

Q. All right. And was this approximately the budget that they were retained to spend on the Fentora launch?

A. I don't recall.

Q. I think we're looking at a number here --

A. I presume it's probably in the range.

Q. It's $890,000; right?

A. Yes.

Q. And was this -- it looks you're debating whether to go forward with -- with retaining

them to do this work for that amount; right?

A. The issue was whether or not we were going -- we were going to retain them. The issue was whether we were going to retain them for all of the activities that are listed here.

Q. All right. And let's go through it. The activities listed, were these the activities that they, in fact, were retained for? Take your time to scan through it, if you would like.

A. These are activities that we discussed. I cannot say whether all of them were implemented.

Q. All right. Well, were a good number of them, at least --

A. Yes.

Q. -- do you recall implemented?

A. Yes.

Q. Thank you.

And Cooney/Waters, they were a PR firm, you were in the PR department at Cephalon. Did they work closely with you in this process?

A. Yes.

Q. And did they report to anyone else or were they working primarily through your department?

A. They were working primarily with me.

Q. All right. And let's just go through this quickly. The first one is launch press materials, media outreach prep, identify, secure Cephalon representative and outside expert.

Is that something that you recall they actually did?

A. 2006 was the initial approval?

Q. Right.

A. I'm sorry. Could you repeat your question?

Q. Yeah. The first item is to identify, slash, secure Cephalon representative and outside expert. Is that something that they actually in fact did?

A. I believe so.

Q. Okay. And stop me, too. So they had actually been the PR firm for Cephalon previously for Actiq; correct?

A. That is correct.

Q. And do you know when they came on with Cephalon?

A. I -- my recollection is that it was approximately in -- sometime in 2000.

Q. All right. So before you got there --

A. Correct.
Q. -- they had already been the PR firm for that company?
A. Correct. It may have been in 2001. Actually, more likely it was 2001.
Q. All right. And do you know who the Cephalon representative and outside experts were that were eventually identified and secured?
A. I don't recall.
Q. Going down to the third one, it says, "Video B-roll package for approval." What is that?
A. So a B-roll is video footage that can be distributed to television outlets.
Q. All right. And was that, in fact, done for Fentora by this company?
A. I suspect it was. I don't recall what it -- what it was. But I suspect that it was. It would have been something we would have done.
Q. And this, again -- all these activities were related to the launch of Fentora, because this is coming -- at least this email is early 2006.
Do you recall if Fentora was approved approximately September of '06; right?
A. That's correct.

Q. And would these activities have started prior to the launch?
A. No. The planning would have started prior to launch, but they would not have been executed until the product was approved.
Q. Go to the next page, page 3. Under "Media Relations," it says, "Conduct" -- kind of moving down, "Conduct trade professional media outreach."
Is that something that Cooney/Waters assisted your department with --
A. Yes.
Q. -- for the Fentora launch?
A. Yes.
Q. If you would just wait for me to finish my question, just so the court reporter can get it all down.
And then below that, "Issues Management." The first one is, "Proactive, slash, PDUFA Date, slash, Approval Preparation."
What is PDUFA?
A. The PDUFA date, that's the date that FDA gives you for the anticipated approval of a product.
Q. And one of the items in that

paragraph is:
(Reading) Develop and implement strategy for communications with third-party organizations and KOLs (end of reading).
Is that a function that they helped your department with?
A. That is correct.
Q. And below that, "Media monitoring," that was something that they helped your department with as well?
A. That is correct.
Q. And below that, "Response letters to the media," one of the items, "Expanding coverage for Actiq, slash, FEBT, slash, breakthrough pain."
FEBT is another name for Fentora; right?
A. That is correct.
Q. And did they assist your department with that?
A. I don't recall if there were inaccuracies that we had to address. They would have helped me if there were inaccuracies, but I don't recall.
Q. So that was -- oh:
(Reading) Draft media letters

responding to inaccuracies and expanding coverage for Actiq FEBT breakthrough pain (end of reading).
So if there were inaccuracies where that needed to be done, they would have helped you with that; right?
A. That is correct.
Q. And the next, page 4:
(Reading) Relationship building, coordination with patient groups, research and consult with groups with which to partner, advise on corporate contributions and ad hoc opportunities, exclude specific collaborations (end of reading).
Could you explain what that function was?
A. We worked to identify patient groups, as defined before, as organizations that represent people who have various conditions. In this case, conditions related to breakthrough pain. And whether -- to see if there were some mutual -- opportunities of mutual interest to both the organization, ourselves. And once we had built relationships with those organizations, what often happens is that scenario is the organization will

choose to submit a grant to you, and so you needed to have a process by which to assess whether or not those grants were approvable by the company.

Q. Okay. And this is something that -- that Cooney/Waters helped you with; right?

A. Cooney/Waters did not help with the relationship building, per se. They helped with what we would consider a landscape assessment, to help identify potential groups that were out there.

Q. And they advise you on corporate contributions to these groups?

A. They would advise on -- if we got a particular contribution, I might have turned to them. I don't recall specifically turning to them, but I could have turned to them to ask their opinion about a particular grant.

Q. About how much to grant the organization?

A. It would not be -- it would not be how much. It would have been whether or not we would recommend to the committee that reviewed these things, that they would be -- we -- our recommendation was to approve them.

Q. And moving down it says:

(Reading) API: A, target chronic pain

initiative, provide support to revise and repurpose target chronic pain materials (end of reading).

What does that mean?

A. The American Pain Foundation had created a booklet called "Target Chronic Pain" that included information about breakthrough pain, and they had requested funding to revise that document and distribute it.

Q. Okay. And then they helped you with that?

A. This, as you can see, is out-of-pocket money. There was no fee associated with that for Cooney/Waters.

Q. All right. So what does that -- so out of pocket in total, what was that money spent on, then?

A. That would be the -- that was our estimate of the grant request that was going to come in from APF.

Q. And then:

(Reading) ACPA, BTP Pamphlet: Provide support to develop and distribute via web or hand print pamphlet on BTP(end of reading).

Did they help you with that?

A. Again, there was no out-of-pocket fee. That was the anticipated amount of the grant request from the ACPA.

Q. All right. And then going to the last page, 5, under "Relationship Building" still:

(Reading) Corporate Contributions and Unrestricted, slash, Educational Grants: Support organization events, slash, activities and include BTP messages and enhance company image in the pain oncology communities (end of reading).

Is that something they helped you out with?

A. This is, again, where we would advise about whether we -- they would advise whether or not there were opportunities in the community to -- to collaborate with organizations or that organizations would submit grants to us.

Q. All right. And then below that, "Professional meetings and nurse advisory board meetings," is that two functions that they helped your department with?

A. Yes.

Q. And what did that entail for these

two?

A. So for the professional meetings, it was helping primarily with scheduling meetings with key opinion leaders and patient groups, and to literally serve as meeting coordinators. Those were meetings that I would attend.

The nurse's advisory board was a meeting in which they would -- they assisted in developing as my agency, in developing the meeting agenda and some of the coordination of the -- the logistics of the actual meeting.

Q. And would you attend those nurse advisory board meetings?

A. It was my -- it was my nurse's advisory board. I was the one who coordinated the nurse's advisory board.

Q. So it was -- nurse's advisory board was developed and created by your department, then?

A. That's correct.

Q. And these professional meetings, these were meetings that were developed and created by your department --

A. That's not correct.

Q. Okay. So were they already meetings that were going to be held?

A. That's correct. It's the American Society of Pain Management Nursing, American Pain Society, American Academy of Cancer -- I can't remember what CPI stands for; it's a cancer organization -- American Academy of Pain Medicine.

These were professional society meetings that were already occurring that Cephalon had nothing to do with. We were using those meetings as an opportunity to understand the community better.

Q. And you said you attended these meetings; right?

A. I did attend those meetings.

Q. Did you talk about breakthrough pain at these meetings?

A. I talked to key opinion leaders about their perspective on breakthrough pain. I did not talk about product.

MR. CRAWFORD: Let's mark the next exhibit, 2081.

(Exhibit No. 23 was marked.)

MR. CRAWFORD: And let's mark the two after that as well, 2085 and 1917. So the exhibits -- I'm sorry; 23, 24, and 25.

(Exhibit No. 24 was marked.)

(Exhibit No. 25 was marked.)

MR. CRAWFORD: Here we go.

Q. We have marked Exhibits 23, 24, and 25. I believe these are all related, but I want you to take a look. The first one is an April 9, 2004 email from Andy Pyfer to a number of people including you, "Re: Important News, New Tools Available." And then there are references to two documents, I believe, or two -- two points here.

And what I want you to let me know, take a look. They are talking about -- let me read it here. It says:

(Reading) Hi, Directors. I have two very important things to tell you about. Please read the entire email (end of reading).

Let's go through this here.

So 1 is:

(Reading) When you have a minute, please check out the link at the bottom of this email. Our PR person for Actiq, Stacey Beckhardt, has been working with the American Pain Foundation (APF) over the last year to develop tools to raise awareness of the importance of assessing and

treating chronic pain, especially BTP as a component of chronic pain (end of reading).

Is that in fact true, that you had worked with the APF over the last year?

A. I think the word "work" is a bit misleading. I did, in fact, speak on many occasions with APF about the need for breakthrough pain and breakthrough cancer pain education, because as a pain organization, they had not been providing patient education in this regard.

We subsequently did provide unrestricted grants for them to work on these projects.

Q. And it says:

(Reading) Through Cephalon support, the APF developed two tools to do just this. They are the Target Chronic Pain Card, which is a clinician-focused tool to assess in assessing and managing pain, and the Target Chronic Pain Notebook, which is a patient-focused pain diary type of tool. Both of these tools were developed by KOL nurses with expertise in pain and supported through grants

of Cephalon (end of reading).

Is that an accurate statement?

A. The projects were supported by grants from Cephalon. I just want to clarify that, not the nurses. The nurses were KOLs, but we did not provide grants to those nurses. So I just want to clarify that.

Q. So were they Cephalon's KOLs, those nurses?

A. I don't know what you mean by a Cephalon KOL.

Q. Okay. Were they --

A. They were key opinion leaders in the -- in the field.

Q. But were any of them paid by Cephalon in any way?

A. Some of them were and some were on our nurse's advisory board.

Q. And some of these nurses, in fact, helped develop these materials; right?

A. Yes. And some of them were involved in our clinical trials. And so they -- they had long-standing expertise in the field of breakthrough pain, and they were cancer specialists as well as pain management specialists.

Q. All right. Then it says:
(Reading) Unfortunately, we will not be permitted to have our reps disseminate these tools. However, we will be able to provide our reps with order forms so that their pain clinics' offices may order them from APF for use in their practices. Each rep will receive examples of each tool and order forms in the very near future (end of reading).
Do you if in fact that was done, providing these reps with these order forms to order -- so their -- the people called upon could order from the APF?
A. I don't know if that was done.
Q. And can you look at Exhibit 25. This is an educational grant draft request; correct?
A. Yes.
Q. And this is one that you -- if you look at the fourth page, that's your signature; correct?
A. That is my signature, yes.
Q. What is this form here? Is this a --
A. This form on page -- this next page?

Q. 4, yeah.
A. This is an educational grant request form. We had a committee that reviewed grant requests that included at this time scientific communications, medical affairs, and our compliance person from legal and government affairs.
Q. All right. And you -- this is your signature; right?
A. Yes.
Q. Okay. And this is a grant -- Cephalon was the only sponsor of this program; correct?
A. To my memory, we were the only sponsor of this program.
Q. And it was a grant of $75,500; correct?
A. That's correct.
Q. And that was to disseminate patient education and related materials; correct?
A. That is correct.
Q. And attached to the request are the materials; correct?
A. If I may look at this for a second, please. This was a request to reprint existing materials.

Q. All right. And Cephalon was going to pay for its dissemination; right?
A. That was the grant request, yes.
Q. And were these the materials referenced by Mr. Pyfer in point 1 of his email?
A. Yes, they are.
Q. And did you get a chance to review these materials before they were disseminated?
A. We did not have a chance to review the materials before they were finalized, because they were finalized, and we were asked for an additional grant for dissemination.
Yes, we did review the materials to make sure that they had no product reference and that they were just disease state education.
Q. And disease state meaning breakthrough pain was one of the disease states; right?
A. That is correct.
Q. Okay. Turn to page 3 of the first handout. On the right-hand column these are the disease states that you're referring to; right? It says:
(Reading) Chronic pain lasts beyond the usual healing time for an illness

or injury. It can last for months to years. At times it can go away completely or it can remain constant. Types of chronic pain, colon (end of reading).
And then it lists three: Intermittent pain, persistent pain and breakthrough pain; right?
A. That's correct.
Q. And are those three pains types of chronic pain, in your view?
A. Yes.
Q. And one of them is breakthrough pain; right?
A. That's correct.
Q. And breakthrough pain was treated by Fentora and Actiq; right?
A. That is correct.
Q. And those were the only two products on the market at this time that treated breakthrough pain; right?
A. That is correct.
MR. JAMES: Objection.
BY MR. CARTMELL:
Q. And, in fact, they were only approved for cancer breakthrough pain; right?

A. That is correct.
Q. But there's no reference at all anywhere in this paragraph that -- to cancer; right?
A. That is correct, because this is disease awareness. It was not about our products.
Q. And this is a brochure that's intended for the patient; right?
A. The first section of this is intended for -- for people living with chronic pain and acute pain, yes. They are intended for patients. The last two pages of this document were intended by the American Pain Foundation to be a companion piece that they -- they themselves, not Cephalon, would disseminate to healthcare professionals to facilitate a dialogue between healthcare professionals and patients about chronic pain.
Q. So you're talking about the document at page --
A. -46 and -47.
Q. And that was intended for physicians; right?
A. And other healthcare professionals, yes.
Q. And the one for patients has no reference to any risk of addiction; correct? From

any pain -- any opioid pain medication; right? Strike that.
And then let's take a look at Exhibit 24. Looking at a paragraph 2 first of 23. Mr. Pyfer writes:
(Reading) Another incredibly important tool has been developed by Stacey in PR. This tool is a nonbranded BTP brochure entitled, "Breakthrough Pain: Do you still have pain?" And it should serve as a tremendous complement to a nonbranded BTP posters and table cards in raising awareness of BTP in your pain clinics, slash, offices (end of reading).
Is that accurate, that that was a tool that you developed?
A. That is correct.
Q. And why did you develop this tool?
A. I was asked to create materials that would help awareness of breakthrough pain.
Q. All right.
A. In the patient community.
Q. And who asked you to do that?
A. It was consistent with the marketing

strategy.
Q. And that included the -- we're in 2006 here. Was that -- was that a marketing plan for Fentora to do that?
I'm sorry. Strike that.
All right. So what we marked as 24, you have written here to Paula Castagno:
(Reading) Paula, pretty sure this is the final version of the brochure. I left you a detailed message about the ACPA brochure. To recap, I would be happy to facilitate. But would you first like -- but would first like to know if you have had the opportunity to talk to PDRC about the concept (end of reading).
Then going on below:
(Reading) In addition, I wanted to remind you that we have other PR pieces that could possibly be repurposed, e.g., a glossary that needs a couple minor updates and a BTP fact sheet prepared by the media and that have already received PDRC approval, Stacey (end of reading).

And what I want to ask you, is the attached "Breakthrough Pain: Do you still have pain?" is that the piece that you are talking about repurposing?
A. No.
Q. Okay. So why -- why did you attach this piece to this email?
A. Because I was asked to provide a final version of a particular brochure that I worked on.
Q. And did you work on this brochure?
A. Yes, I did.
Q. Okay. And is this the same brochure that's referenced in Exhibit 23?
A. Yes, it is.
Q. And I'm just trying to understand. So what was -- why were you blowing the dust off it here in this email? This is 2006 in this email. Exhibit 24.
A. I -- I don't recall why the team was interested in using it again.
Q. So this is the -- this is the brochure that Mr. Pyfer is referencing in this -- and you prepared this at somebody's direction with regard to the market strategy for Fentora; right?
A. It was consistent with the marketing

strategy, yes.
Q. And what I want to ask here is at the time you prepared this in '04, Actiq was the only medication approved for any kind of breakthrough pain; right?
A. That is true.
Q. And -- but it was only approved for cancer; correct?
A. That is correct.
Q. And is there any reference in this brochure about cancer?
A. There are examples of -- there are examples. The examples, for example, on page -- your page -745 in the first column, the bottom paragraph, talks about cancer patients' breakthrough pain flares can peak in as little as three to five minutes and last about 30 minutes. Those were all based on cancer-related data. And it specifically gives the reference to cancer.
Q. But it doesn't say it's only approved for cancer; correct?
MR. JAMES: Objection.
THE WITNESS: This is not a disease -- brochure that was intended to talk about product. It only talks about disease state.

BY MR. CRAWFORD:
Q. But it does convey to the patient here that there is a product to treat the breakthrough pain; right?
A. I'm not sure I understand where you're referring to.
Q. Well, I mean, this -- the purpose of this brochure is to educate and make patients aware that there might be some kind of treatment or medication for their breakthrough pain; right?
A. The purpose --
MR. JAMES: Objection.
THE WITNESS: The purpose of the brochure was to make patients aware of whether or not they were experiencing breakthrough pain. We did not market direct to patients. It was not appropriate to talk to them about treatments in this -- in this kind of brochure.
BY MR. CRAWFORD:
Q. So how was a brochure supposed to be put into the hands of the patients? Is it as Mr. Pyfer references here in his Exhibit 23?
MR. JAMES: Objection.
THE WITNESS: The brochure was intended to be -- originally was intended to be provided to the

sales force, as suggested here, for distribution, not by Cephalon, but by physicians who chose to distribute the brochures.
BY MR. CRAWFORD:
Q. So he says:
(Reading) We will be shipping a boatload (500 brochures) of these to each rep along with the brochure holders, only 15 initially due to manufacture constraints, et cetera, in the second quarter shipment, so that they can be utilized in patient waiting rooms to raise awareness of BTP. Considering the incredible historical impact of the nonbranded BTP posters and table cards, I believe that this tool may be the most important, quote, sales aid, unquote, we develop this year. Please encourage your reps to utilize these brochures in every clinical -- clinic office possible. The more patients and clinicians talk about BTP, the greater chance we have at being prescribed (end of reading).

So really this was intended by the company then to be a sales aid to be left in the doctor's office of either -- by the doctor or through the sales of giving it to the doctor; right?
MR. JAMES: Objection.
THE WITNESS: After I developed the materials, Andy Pyfer thought that that was a good way to disseminate the materials.
BY MR. CRAWFORD:
Q. So if you turn to page -46 on the bottom here.
A. Yes.
Q. There is a box says:
(Reading) Get rid of common myths about pain. Asking for pain medicine is not a sign of weakness. Side effects of pain medicines can be managed. Concerns about addiction should not prevent proper pain management (end of reading).
So this box is a reference -- is intended to be a reference to the patient that there are medications available and they shouldn't have to worry about addiction; right?
MR. JAMES: Objection.

THE WITNESS: It does not say you shouldn't worry about addiction. It suggests that you may -- you should not be so afraid of addiction that you don't seek out pain management.

BY MR. CRAWFORD:

Q. And, again, the whole disease state that is being conveyed here is breakthrough pain; right?

A. That's right. With examples from cancer patients.

Q. But it doesn't say it's only for cancer patients in the --

A. That's correct.

Q. All right. I just want to mark the next -- actually, what I think I will do is mark the next three exhibits. So we're marking 26, 27, and 28.

(Exhibit No. 26 was marked.)

(Exhibit No. 27 was marked.)

(Exhibit No. 28 was marked.)

MR. CRAWFORD: How many minutes do I have left?

MR. WOLFE: I've got you at 16 minutes.

MR. CRAWFORD: 27. And 28.

Q. This is a series of three exhibits.

I just want to have you identify them and whether this is accurate.

So 26 is an educational grant request for $33,800 to the American Chronic Pain Association. It's dated in September 2006. And this -- again, this is one that you signed off on on the next page, -594; correct?

A. That is correct.

Q. And -- and this was to -- for a "patient brochure and radio media tour on BTP during September Pain Awareness Month to be developed, slash, sponsored by a patient advocacy group"; is that correct?

A. That is correct.

Q. And this is, again, right before the launch of Fentora that this was approved, right, by this committee?

A. I'm sorry.

Q. Was this approved -- when it's signed off by the committee, does that mean it was approved?

A. Yes.

Q. Okay. And it was approved just about when Fentora was approved and launched; right?

A. Yes. That is correct.

Q. And what I want to ask here is, we

marked Exhibit 27. It's an email from Katherine Collier with CCTU dated October 2nd, 2006, APA -- ACPA brochure, the attachment is "Breakthrough pain 9-20-06 PDF."

Is this the brochure that came out of this grant?

A. Yes, it is.

Q. Okay. And 2076, is that a color copy of it?

A. This -- 28?

Q. I'm sorry. 28, yes.

A. Yes, that is a color copy of the brochure.

Q. All right. And the purpose of this brochure, what was it supposed to -- who is it supposed to be disseminated to? Patients, correct?

A. It is a patient -- it is a patient brochure.

Q. And this was going to be disseminated by the ACPA; correct?

A. That's correct.

Q. And that's the American Chronic Pain Association; right?

A. That is correct. It is a patient organization.

Q. And the title of the document or the brochure is, "Managing Breakthrough Pain, BTP"; is that right?

A. That's correct.

Q. And that was -- as we had seen, that is a type of chronic pain; right?

A. Yes, it is a type of chronic pain.

Q. And --

A. But it is a type of chronic pain that is managed on top of -- of around-the-clock pain.

Q. And in this patient brochure, there's nothing in this brochure that talks about the risk of addiction; correct?

A. That is correct. It is a disease awareness brochure. It is not a -- it's not a brochure about product.

Q. But it does say on the second page, second column, it says:

(Reading) Talk to your doctor about medication that might help during BTP episodes. When using pain medications for BTP, the goal should always be improve pain relief and improve function (end of reading).

So the only medication on the market at this

time would have been Fentora and Actiq, both -- both products made by Cephalon; right?
MR. JAMES: Objection.
THE WITNESS: That is correct. This -- this brochure was -- was developed independent of our input.
BY MR. CRAWFORD:
Q. But the intention was to fund a brochure and a radio media tour on BTP that would be released during Pain Awareness Month in September; correct?
A. That is correct.
Q. And if you look at Exhibit 27, there's a reference to a radio media tour on breakthrough pain with Penny Cowan as the person with pain and Dr. Knox Todd, professor of emergency medicine.
Knox Todd was a paid Cephalon consultant; correct, at this time?
A. I do not -- I do not believe so, but I don't know that for sure. He was on the Board of Directors of ACPA which is how Penny Cowan knew him.
Q. All right. And was -- the intention was that some of these funds would be used from the grant to pay Dr. Todd for his services --

A. No.
Q. No? So how -- did he get compensated in any way for doing that radio media tour?
A. Not to the best of my knowledge.
Q. So he did it free?
A. He's on the board of directors of a patient advocacy organization, so yes.
Q. Does he get paid as a member of the board?
A. No, he does not.
MR. CRAWFORD: Now I want to mark two more exhibits. That will be 29 and 30. How much time do I have?
MR. WOLFE: Ten.
(Exhibit No. 29 was marked.)
MR. CRAWFORD: So 1930 and 2040.
Q. I have marked here another Educational Grant Draft Request for the American Pain Foundation. The amount is $25,000. "Type of program PR: Patient-focused book on treatment options to be developed by a patient advocacy group." It's signed off in about -- in September of '06.
That's about the time that Fentora was approved; right?
A. That's correct.

Q. And you signed off on this on the next page; right?
A. I signed off on this as the submitter, yes.
Q. And then attached to it is a letter dated May 10th, 2006, from the American Pain Foundation, Wilbert Rowe, and he is asking for $25,000 to distribute American Pain Foundation's new book, "Treatment Options for Pain"; correct?
A. To produce and distribute.
Q. And so this grant is to fund the -- is it to fund the production of the book and distribution or just the distribution?
A. Production and distribution, which is an important distinction. We had not seen any of the content when we gave this grant.
(Exhibit No. 30 was marked.)
BY MR. CRAWFORD:
Q. So but -- okay. So let's take a look. It is Exhibit 30. Is that the book that was eventually produced out of this?
A. Yes.
Q. Okay. And if you take a look at the book, it does say at page -499 that Cephalon made contributions to this; correct?

A. Financial contributions. Not content contributions.
Q. Okay. But if you look at page -501, it says:
(Reading) American Pain Foundation Board, reviewer -- physician reviewers, Dr. Scott Fishman and Dr. Russell Portenoy (end of reading).
Do you see that?
A. That's correct.
Q. And they were Cephalon-paid consultants; correct?
A. They were certain points in time that they were compensated for certain work that they did. They were both unpaid board members of the American Pain Foundation.
Q. But they were paid by Cephalon at some point as consultants; right?
A. For specific projects that they did. Russ Portenoy, for example, was a clinical investigator for the company.
Q. How about Dr. Fishman, was he paid to be a KOL by Cephalon?
A. Dr. Fishman was a KOL, is a KOL. He is one of -- the two of these are two of the most

prominent pain specialists in the country. I don't remember specifically Dr. Fishman being compensated by Cephalon. I just don't recall. I know that we did some projects with him, but I do not specifically recall him being compensated for those projects.

Q. So you're not sure if he was a paid KOL by Cephalon or a paid speaker?

A. That is correct.

Q. All right. And if you could go to -516, this page does talk about breakthrough pain; correct?

A. Where are you reading?

Q. I'm sorry. -516, in the bubble it would be. It's a little hard to read. But it says -- it's up on the screen --

(Reading) Pain is considered breakthrough pain when it breaks through the pain medication being used to treat persistent pain.

Breakthrough pain, BTP, can occur suddenly in bursts and may last for short periods of time. BTP can also be experienced during pain-producing activities. BTP can result when the dose of a long-acting opioid begins to

wear away (end of reading).

And that -- did I read that correctly?

A. Yes, you did.

Q. And it does say next to the bubble:

(Reading) Fentanyl is also available in a losange. In this formulation it has a quick on set and short duration of effect that makes it especially useful for the treatment of, quote, breakthrough, unquote, pain (end of reading)?

Right? And at this time, when this publication comes out, or at least when you've attached it, Fentora and Actiq are the only two breakthrough pain medications out there; right?

A. That is correct.

Q. And they are only approved, as you acknowledge, for cancer pain; right? Cancer breakthrough pain?

A. That is correct.

Q. And no -- there's no reference here that this drug that's being referenced is only approved for cancer breakthrough pain; is there?

MR. JAMES: Objection.

THE WITNESS: The content of this brochure

was not created by us. It was created by a patient organization.

BY MR. CRAWFORD:

Q. But with reviewers who at some point, at least one of them that you're aware of, was paid by Cephalon, right, Dr. Portenoy?

A. This brochure includes reference to a number of medications, to my memory. I haven't had a chance -- I know we're short on time. But if you look through it, it refers to a lot of medications, not just breakthrough pain medicines. This was intended as a broad look at the field of pain medicine from a patient perspective.

Q. One of the medications it's referring to is breakthrough pain medication, which at the time was only Fentora; right -- and Actiq?

A. That is correct.

Q. And Cephalon, at least in part, funded the creation and distribution of this booklet; right?

A. We were one of the funders, yes.

MR. CRAWFORD: Let me just check my outline here.

All right. That's all I have. Thank you.

THE WITNESS: Thank you.

MR. GASTEL: Do you want to take a quick five-minute break?

THE VIDEOGRAPHER: We are going off the record. The time is 6:53 p m.

(Recess taken.)

THE VIDEOGRAPHER: We are back on the record. The time is seven o'clock p m.

EXAMINATION

BY MR. GASTEL:

Q. Good evening, Ms. Beckhardt, my name is Ben Gastel and I represent plaintiffs in the Tennessee lawsuits that have been cross-noticed into this deposition. And I represent some folks in different cases than the two attorneys who have been asking you questions previously today.

I began all of these examinations with an objection. We have a standing objection about these depositions going forward. I will just lodge it, and we will continue.

But my first question is, is during your work for Cephalon and Teva, did you ever on occasion have chance to travel to the state of Tennessee?

A. Not that I recall. There -- not that I recall.

Q. And let me back up and do one

preliminary thing as well.
Where do you currently live?
A. North of San Francisco.
Q. What is your exact address?
A. [redacted]
Q. How long have you lived there?
A. Three-and-a-half years.
Q. Who lives there with you?
A. My partner, Andrew Litwood.
Q. And then do you have any plans to move in the near future?
A. I do not.
Q. You testified earlier in questioning from Mr. Cartmell that you believe there is an opioid epidemic in this country. Do you recall that testimony?
A. Yes.
Q. How did you form that understanding?
A. I formed that understanding by understanding statistics on abuse and diversion of opioids in general.
Q. And did you form that understanding, at least in part, by reviewing media stories concerning opioid abuse, misuse and diversion?

A. To some extent.
Q. How much of your time when were you working in the public relations for Cephalon would you spend tracking media reports about the company and the company's products?
A. Well, I did have a public relations agency that did a lot of that tracking for me. I didn't have to do that much personally.
Q. Sure. And Cooney/Walters group were some of those -- at one point was that public relations firm; right?
A. Cooney/Waters, yes.
Q. And they would compile what were essentially like weekly reports that they would send to you, and then you would send out to various members of the company regarding media reports about Cephalon, Cephalon's products and opioids in general.
Do you recall those reports?
A. Yes.
Q. And then at some point, Cooney/Waters stopped doing that and another firm called Vox Medica started that?
A. That's right.
Q. Do you recall that?
A. I changed agencies.

Q. And then at some point you would take those -- they would compile those and I assume send them in an email to you, and then you had an internal Cephalon list that you would then distribute those reports out to; do you recall that?
A. Yes.
Q. And that happened on a weekly basis; right?
A. I don't know if it happened weekly. It was frequent, but I don't know if it was weekly.
Q. Sure. And we will look at some of them later and it might refresh your recollection on that.
Did you discuss with those vendors how they put those reports together?
A. I'm not sure what you are asking.
Q. Well, they would compile these media stories; right?
A. Correct.
Q. Send them to you?
A. Correct.
Q. Did you discuss with them how they were doing that?
A. How they were collecting the information?

Q. Yeah.
A. They were monitoring media stories. No, I did not tell them how to monitor the media. They had expertise in that regard.
Q. Sure. But what I'm talking about is physically like how they were compiling those stories? Like how were they monitoring? Did you have those conversations with them?
A. I guess I'm not exactly understanding your question. You're talking about the format in which they were presented?
Q. No, no, no. I'm talking about, how did they learn of the media stories that they then forwarded on to you?
A. They had media monitoring services that they use through their agencies. It was not Cephalon controlled. It was what they -- what they found in the media through their monitoring services.
Q. Sure. And then they would find that, forward it to you, and then you would forward it on to other people in the company?
A. That's correct.
Q. Do you ever recall sending those reports to anyone outside of Cephalon?
A. I don't recall.

Q. From time to time, would employees come to you and ask to be sort of added on to your internal distribution list?
A. I don't recall.
Q. Was there any time that you can recall that someone asked to have access to your distribution list and you denied them access or refused them access?
A. Not that I recall.
Q. Do you recall when Cephalon began receiving those monitoring reports from its PR vendors?
A. I don't recall. But Cooney/Waters -- I started working with Cooney/Waters in 2001, and they were an agency of record prior to that time. So they probably were doing media monitoring from -- as soon as they became an agency. I don't know the frequency in those early years.
Q. From your entire time that you worked for Cephalon and then Teva from roughly 2001 to 2012, was there media monitoring going on during that time period?
A. Not that entire time frame, no.
Q. When was the time frame when it wasn't going on?

A. Under my -- it may have been going on under somebody else's direction. But under my direction, I left my public relations role in approximately -- I guess it was about 2008 or so.
Q. Okay. And then did somebody take back up your public relations role and continue the media monitoring?
A. Yes.
Q. And do you recall who that was?
A. Jennifer Antonochi.
Q. I'm going to hand you a document we will mark as Exhibit 31 to your deposition. If I can find a place to put it.
(Exhibit No. 31 was marked.)
BY MR. GASTEL:
Q. And we will get to your reports with your PR documents. But I want to start with this document, which is an internal email from you to a variety of people inside Cephalon and it's dated March 21st, 2005; do you see that?
A. Yes.
Q. And the subject is, "Time (3/28) Reports on OxyContin Abuse and Diversion in Appalachian, Virginia."
Did I read that correctly?

A. It's in rural Virginia.
Q. It's the subject line of the email?
A. Oh, the subject line. I'm sorry. Yes.
Q. And then you write, as you forward this Time Magazine article in your cover email here that says:
(Reading) Time reports, parentheses, 3-28, end parentheses, on the abuse and diversion of OxyContin in rural Virginia and local law enforcement's efforts to grapple with pill-related crime (end of reading).
Did I read that correctly?
A. Yes.
Q. And those were your words; right?
A. "Grapple with pill-related crime"?
Q. Well, what I'm saying is --
A. That was a quote from the magazine.
Q. Sure. But this is a portion of the email that you wrote; correct?
A. That is correct.
Q. And it says:
(Reading) Primarily an overview of the problem and law enforcement's

response. The article does not contain any new information about OxyContin abuse (end of reading).
Did I read that correctly?
A. Yes.
Q. When you say it "does not contain any new information about OxyContin abuse," is that because you were already aware as early as 2005 that OxyContin was being abused across the country?
A. What it suggests is there had been information in the media about the use of OxyContin, but that -- that's all I can say, because that was not my product. And I was not involved in any way with OxyContin.
Q. Sure. But you thought it was important, at this point at least, to take this article and forward it on to your colleagues inside the company; right?
A. Because we forwarded articles having anything to do with opioids or abuse and addiction situations, regardless of what the product was, so that we understood the landscape, and we were in a better position to understand whether other risk management issues were needed through our Risk Management Program.

Q. Sure. I want to read a little bit of this article. First paragraph of the article states:

(Reading) Folks in Tazewell County know they better keep their eyes open, their tool sheds locked, and their barn doors shut. Junkies addicted to prescription pills and looking for anything to steal to pay for their next fix have turned this 520 square mile patch of Appalachian Virginia, a bucolic tangle of wooded mountains, steep hills and rolling pastures dotted with sagging barns and country churches, into a society plagued by pilferers (end of reading).

Did I read that correctly?

A. Yes, you did.

Q. I don't want to question you too much on U.S. geography today. But are you aware northeast Tennessee and this part of rural Virginia intersect?

A. Yes.

Q. So you know that this is an area that's very close to Tennessee; correct?

A. That's correct.

Q. The article goes on to state that,

again, beginning at the third paragraph:

(Reading) Federal authorities are at a loss to explain why prescription pill abuse pops up in some places and not in others, and while places like central Maine, eastern Kentucky and southwestern Virginia where OxyContin abuse first emerged as a problem are awash in drug-related crime (end of reading).

Did I read that correctly?

A. Yes, you did.

Q. Was that your understanding of the opioid epidemic, that it popped up in some places and not others?

A. The data which I saw seemed to suggest that there were some places where there were more -- there was more abuse than others. We did not see that with Actiq or Fentora, any patterns of that type.

Q. Sure. And what I'm getting at here is that you were aware, at least as early as 2005, that the problem with opioid abuse was particularly acute in Appalachian counties in that area around that geographic region?

A. Not related to our product. But I was aware there was a general problem in that geography, yes.

Q. Sure. Continuing with this article, the next paragraph begins:

(Reading) It has taken seven years for the full measure of the pill's stranglehold on Appalachian counties like Tazewell to become obvious -- in clogged and crowded courts, in villages whose jails are so full that inmates sleep on the floor, and in neighborhoods focused on leaving nothing valuable lying around.

The number of robberies, burglaries, and thefts has shot up 48 percent in Tazewell in only five years, from 483 crimes in 1998 to 716 in 2003, even as the national property crime rate fell 25 percent (end of reading).

Did I read that correctly?

A. Yes, you read that correctly.

Q. Was that your understanding of the opioid epidemic, that it was resulting in increases in crimes in communities that were under its spell?

MR. JAMES: Objection.

THE WITNESS: I was aware of media reports. But I was not aware of our products being implicated in those situations. Because, as I said, we had no evidence to suggest that we had geographic clusters.

BY MR. GASTEL:

Q. Sure. And then closing out this article, if you flip to the next page, second-to-last paragraph of the article. It says:

(Reading) State and local officials are building institutions virtually overnight to grapple with pill-related crimes. Three regional jails are set to open this spring to ease inmate crowding in the state's Appalachian corner and the Virginia general assembly recently appointed another circuit judge to help Tazewell (end of reading).

Did I read that correctly?

A. You read that correctly.

Q. Was it your understanding that state and local officials were having to expend funds to deal with the opioid epidemic when they were encountering problems with the opioid epidemic?

A. No, that was not my memory.
(Exhibit No. 32 was marked.)
BY MR. GASTEL:
Q. I am going to hand you a document that we will mark as Exhibit 32. And this is an email from Jacqueline Davis, sent to a variety of people. And if you look on the second-to-the-last line of the "To" field, you will see your name.
A. Yes.
Q. Do you see that?
A. Yes, I do.
Q. And if you look about a quarter of the way down, it says:
(Reading) Weekly Pain Monitoring Report, compiled by Cooney/Waters Group (end of reading).
Did I read that correctly?
A. Yes.
Q. Does that refresh your recollection that you received these reports weekly at least around this time period?
A. Yes. As I indicated before, it was my -- that seemed about right, but I wasn't sure exactly how frequently they came out.
Q. Sure. And the -- the pain monitoring

report here has a section that's in bold called, "Abuse addiction and diversion." Do you see that?
A. Yes.
Q. And under that is a bullet point that says:
(Reading) Reuters reported on the U.S. Justice Department's National Drug Intelligence Center study that identifies drug threats for 2007. One alarming trend is that opioid users are increasingly seeking heroin because of law enforcement's crackdown on the abuse of prescription narcotics (end of reading).
Did I read that correctly?
A. Yes, you did.
Q. Then if you go later on in this exhibit to the page with the end Bates label of -763. Do you -- are you with me?
A. Yes.
Q. There at the bottom of the page it actually includes that Reuters article. Do you see that?
A. Yes.
Q. And it says:

(Reading) A crackdown on illegal use of prescription narcotics like the powerful painkiller OxyContin has caused some addicts to switch to heroin, a Justice Department report said on Wednesday (end of reading).
Did I read that correctly?
A. Yes, you do.
Q. Then it goes on to state that according to -- I'm sorry, in the third paragraph it says:
(Reading) In some areas, such substitutions among prescription drug abusers have been widespread, creating new challenges for local law enforcement and public health agencies compelled to address a widening local heroin user population (end of reading).
Did I read that correctly?
A. You read that correctly.
Q. And then the next paragraph:
(Reading) The study also found rates of pharmaceutical drug abuse, including pain relievers,

tranquilizers, stimulants and sedatives exceed that of all other drugs, except marijuana (end of reading).
Did I read that correctly?
A. Yes, you did.
Q. And then the report goes on to say:
(Reading) According to reports from California, Florida, Michigan, Ohio and Wisconsin, some opiate abusers in that state who began using OxyContin have switched to heroin (end of reading).
Did I read that correctly?
A. You read that correctly.
Q. In your understanding of the opioid epidemic, did you come to understand that some users would switch over from using a prescription opioid like OxyContin to using a nonprescription opioid, like heroin?
A. I was aware of media reports to that regard. Because I did not work for Purdue Pharma, I have no idea what their pharmacovigilance data were suggesting.
Q. sure. And then the article on the

next page at the top says:
(Reading) Nearly 79 percent of state and local law enforcement agencies reported high or moderate availability of diverted pharmaceuticals in their area (end of reading).
Did I read that correctly? I'm sorry. At the top of the page.
A. Yes.
Q. -764. And then it goes on to say:
(Reading) Demand for the drug has remained high with use by an estimated 15,172,000 people (end of reading).
Did I read that correctly?
A. You read that correctly.
Q. Are you troubled by that number, 15,172,000 people?
A. Yes.
Q. It's a staggering number, would you agree with me?
A. It's a large number. But it's unrelated. It is not an article that refers to our products.
Q. Well, that's a fair point. And then if you go back to the first page of this email,

there's a Wall Street Journal article referenced there that actually does reference a Cephalon product. It's entitled, "Off-label use of potent narcotic Actiq growing raising concern."
Do you see that?
A. Yes.
Q. And then again, that article is also attached in this. And it appears on the page Bates labeled -762.
A. Yes.
Q. And it's an article that apparently was originally printed in the Wall Street Journal but also reprinted in the St. Paul Pioneer Press on November 15, 2006. Do you see that?
A. I see that.
Q. And it says, "While" -- it begins:
(Reading) While pregnant with her second child three years ago, Tiare Frontera suffered from bad migraines (end of reading).
Did I read that correctly?
A. Yes.
Q. (Reading) A neurologist prescribed Actiq, a berry-flavored lozenge on a stick that looks and tastes like a

lollipop. After a few sucks on the medicine, she says a rush of euphoria washed her headache away (end of reading).
Did I read that correctly?
A. You read that correctly.
Q. And then it says:
(Reading) Soon, Frontera, who had struggled with addictions to milder narcotics, was consuming five Actiq lozenges a day. When she gave birth, her baby son was cranky and wouldn't sleep. Doctors told her he had become addicted to the drug and was in withdrawal (end of reading).
Did I read that correctly?
A. Yes, you did.
Q. That describes an incident of what's called neonatal abstinence syndrome, also known as NAS. Are you familiar with that?
A. Yes.
Q. And you're familiar that if pregnant women use opioids while pregnant, that that can result in their baby being born with addiction; do you understand that?

A. Yes.
Q. The articles goes on to say:
(Reading) Frontera is one of thousands of Americans who are prescribed Actiq, an extremely potent narcotic for ailments that have nothing to do with its intended use. The Food and Drug Administration approved the drug eight years ago for use in cancer patients who suffer intense bouts of pain that other narcotics don't relieve (end of reading).
Did I read that correctly?
A. Yes, you did.
Q. When you received this article or received this from your PR vendor, did you agree with that statement?
A. Which aspect of the statement?
Q. That "The Food and Drug Administration approved the drug eight years ago for use only in cancer patients who suffer intense bouts of pain that other narcotics don't relieve."
A. We understood the -- the statement "intense bouts of pain" to mean breakthrough pain. And if that is what the John Carribrew is referring

to, then yes, that is a correct statement.
Q. And then do you agree with his characterization that Actiq is an extremely potent narcotic?
A. Actiq is a Schedule 2 opioid.
Q. And then the article goes on to say:
(Reading) In the first half of this year, oncologists accounted for only one percent of the 187,076 Actiq prescriptions filled at retail pharmacies in the United States (end of reading).
Did I read that correctly?
A. Yes, you did.
Q. Did you -- in 2006, when you received this article, were you concerned that, according to this, there was only one percent of Actiq prescriptions from oncologists?
A. We were aware the rates of prescribing by oncologists were low. I personally was not aware it was that low.
Q. And then skipping the -- skipping down to the paragraph beginning, "Actiq's broad off-label use."
A. Yes.

Q. It says:
(Reading) Actiq's broad off-label use raises questions about whether those restrictions are sufficiently protecting patients. We all know Actiq is being misused and abused as Brian Sweet, a manager in the pharmacy unit at health insurer WellPoint, Inc. After witnessing a surge in Actiq prescriptions, WellPoint cracked down by making doctors show that patients being prescribed the drug have cancer (end of reading).
Did I read that correctly?
A. You read that correctly.
Q. And that sort of dovetails with your testimony earlier when Mr. Cartmell was asking you questions about Actiq's broad off-label use; correct?
MR. JAMES: Objection.
THE WITNESS: That is correct.
(Exhibit No. 33 was marked.)
BY MR. GASTEL:
Q. I hand you a document that we will mark -- I always tell myself I'm not going to mark the wrong one, but then I always do at least once.

This is 33.
Ms. Beckhardt, this is another one of the Cooney/Waters Weekly Pain Monitoring Reports that you sent around to various Cephalon employees on February 16, 2007. Do you see that?
A. Yes.
Q. And if you flip over to the second page, there is a reference to an Associated Press report. Do you see that?
A. Yes.
Q. And it says:
(Reading) The Associated Press featured a report by John Walters, director of the Office of National Drug Council, that found while marijuana use among teenagers has declined, U.S. teens are still abusing prescription drugs at a steady or, in some cases, increasing rate (end of reading).
Did I read that correctly?
A. You read that correctly. But it's not referencing our products directly.
Q. Sure. It says:
(Reading) Increased use of both

OxyContin and Vicodin are noted (end of reading).
Did I read that correctly?
A. Yes.
Q. And then, once again, it attaches the report. Again, if you flip to the Bates range -672, you will see the Associated Press report. And it begins -- are you there? I'm sorry. I don't want to go too fast.
A. -672, about Associated Press?
Q. Yeah. "Teens using prescription drugs." Do you see that?
A. Yes.
Q. The article begins:
(Reading) Junior has been helping himself to mother's little helper (end of reading).
Did I read that correctly?
A. Yes.
Q. It says:
(Reading) That's the conclusion of a report released Wednesday by White House drug czar John Walters that found while U.S. teenagers use of marijuana is declining, their abuse of

prescription drugs is holding steady or, in some cases, increasing. The drug dealer is us, said Walters, the national drug policy director (end of reading).

Did I read that correctly?

A. Yes, you read that correctly.

Q. And then on the next page, it says:

(Reading) According to an analysis of the national surveys prepared by Walters' office, 2.1 million teenagers abuse prescription drugs in 2005, most year for which figures are available (end of reading).

When you received this, did you believe that that was an accurate figure?

A. I didn't have the ability to question it or verify it.

Q. Sure. But it came -- that number apparently comes from a report from the White House drug czar, John Walters, according to the article; correct?

A. That's correct.

Q. And the article closes out with a reference to a Dr. Terry Horton, the medical director

of Phoenix House, which operates nearly 100 substance abuse programs in nine states. He said:

(Reading) That belief that prescription drugs are safer than street drugs is false (end of reading).

Did I read that correctly?

A. You read that correctly.

Q. It says:

(Reading) These medicines cause dependence and addiction when misused and have the potential to cause death, he said (end of reading).

You agree with that statement; correct?

A. All Schedule 2 opioids have the -- that ability.

Q. It says:

(Reading) We're talking about medicines that are related pharmacologically to heroin and have very similar effects (end of reading).

Correct?

MR. JAMES: Objection.

THE WITNESS: It's what it says.

///

BY MR. GASTEL:

Q. Oh, I'm sorry. Did I read that correctly?

A. You read it correctly.

Q. And this is an article that references OxyContin and Vicodin; correct?

A. Yes.

Q. And then this particular one also -- this particular monitoring report also has a New York Times article with it -- or, I'm sorry, a USA Today article.

A. And where is that, please?

Q. It's February -- I'm sorry, it's on the page ending in -671.

A. Okay. Thank you.

Q. The top of the page. It says:

(Reading) Pain killer more available for abuse (end of reading).

Do you see that?

A. Yes.

Q. And it says:

(Reading) Methadone prescriptions grow, adding to U.S.A.'s illicit drug trade (end of reading).

Did I read that correctly?

A. Yes, you read that.

Q. And then if you go down to the very -- the second-to-last paragraph that's on this page, it says:

(Reading) With more prescriptions, there's more methadone in the supply pipeline, Curry says, and, therefore, more chance the drug will wind up for sale on the street (end of reading).

Did I read that correctly?

A. You read that correctly.

Q. Do you agree -- and I think that you testified that you did earlier with Mr. Cartmell -- that when you have more prescriptions, that leads to more supply, and, therefore, a greater likelihood that these prescription opioids will end up illegally on the street; do you agree with that?

MR. JAMES: Objection.

THE WITNESS: I didn't suggest that they would be used -- that they would get illegally on the street. I do think that they're -- I did suggest that if you increase the number of prescriptions, there is a possibility that there may be more inappropriate use, whether it be diversion or misuse.

But these -- this methadone is a totally

different product than Actiq and Fentora, and we did not see these same patterns that we were seeing with other opioids.

BY MR. GASTEL:

Q. Sure. And then on the next page, the article goes on to describe that:

(Reading) The NCHS study identified 12 states as having especially significant increases in methadone-related fatalities from 1999 to 2004 (end of reading).

Do you see that?

A. Yes.

Q. And it identifies Tennessee as one of those states; correct?

A. That is correct.

(Exhibit No. 34 was marked.)

BY MR. GASTEL:

Q. I hand you another exhibit that we will mark as Exhibit 34. Once again, one of these Weekly Pain Monitoring Reports from Cooney/Waters Group that you sent to your internal Cephalon distribution list on Saturday, August 11, 2007. Do you see that?

A. Yes.

Q. And, again, it carries the heading, "Abuse, addiction and diversion."

A. Yes.

Q. And it references a Reuters article; do you see that?

A. Yes.

Q. And also a USA Today article under the bullet point 6. Do you see that?

A. Yes.

Q. Let's go to the USA Today article. It's from August 5th, 2007 -- oh, I'm sorry, it's on the Bates label page ending in -231.

A. Okay.

Q. Are you with me?

A. Yes.

Q. And it says -- and it's entitled "Rising pain killer abuse reveals itself in damaged lives." Do you see that?

A. Yes.

Q. And it begins:

(Reading) When his cravings for painkillers got to be too much, Steve Dotson lay down and let his wife drive a car over his leg. It hurt, but he didn't think about the pain. He

concentrated on the medicated bliss that would follow (end of reading).

Did I read that correctly?

A. Yes, you did.

Q. Dropping down three paragraphs:

(Reading) With the -- With 124 million prescriptions in 2005, hydrocodone is the most often prescribed opiate pain killer on the market sold under hundreds of brand names and generic titles. All are combination products, meaning they combine hydrocodone with another ingredient (end of reading).

Did I read that correctly?

A. You read that correctly. And those are not our medications.

Q. Sure. And then, "In Central Appalachia, prescription pain killer" -- oh, I'm sorry, I'm dropping down -- one, two, three, four, five -- six paragraphs.

(Reading) In central Appalachia, prescription painkillers first became a national concern five or six years ago. Then the drug-causing alarm was oxycodone, particularly under brand

name OxyContin, which became infamous as hillbilly heroin (end of reading).

Did I read that correctly.

A. You read that correctly.

Q. And it goes on to say:

(Reading) As OxyContin came under scrutiny, doctors were more careful about how they prescribed it. Many switched to hydrocodone products which were already popular but didn't have the same stigma (end of reading).

Did I read that correctly?

A. You read that correctly.

Q. (Reading) All 50 states saw increases in the distribution of hydrocodone between 2001 and 2005, but the trend was particularly significant in the south, where Tennessee and West Virginia saw three digit rates of increases (end of reading).

Did I read that correctly?

A. You did. But I repeat, it has -- it's not related to Actiq and Fentora.

Q. Sure. And so then the next paragraph:

(Reading) The ten states where hydrocodone is highest are all southern states, according to the DEA. And the four of the top five, Tennessee, West Virginia, Kentucky, and Alabama, are in Appalachia (end of reading).

Did I read that correctly?

A. Yes.

Q. I think folks in Alabama might be a little surprised that this article considers themselves part of Appalachia, but --

A. Having lived -- having lived in Alabama myself, I probably would question that.

Q. Sure. And that's just another article describing the opioid epidemic in places like the south, like in Tennessee, that were particularly hard hit by the opioid epidemic; right?

MR. JAMES: Objection.

THE WITNESS: It is another media story.

BY MR. GASTEL:

Q. That describes problems with opioids in the south; right?

A. That is correct.

(Exhibit No. 35 was marked.)

BY MR. GASTEL:

Q. I will hand you -- I'm going in order right now.

MR. WOLFE: If you skip one, let me know.

MR. GASTEL: I will let you know.

Q. This is another one of the Weekly Pain Monitoring Reports, but this one has apparently been compiled by Vox Medica.

A. That's correct.

Q. And it's dated May 30th, 2008, but once again it's something you distributed to your internal Teva list; right? Well, Cephalon list at the time; right?

A. Cephalon, yes.

Q. And, again, it has yet another reference to suspected abuse and diversion; do you see that on the second page?

A. Yes.

Q. And it references an Associated Press story and an Arizona family dot com story. Do you see that?

A. Yes.

Q. Once again, those stories are attached. And the Associated Press story from May of 2008 concerns a pro wrestler who killed himself and

his wife and his seven-year-old son as a result of prescription pain killer addiction; do you see that?

A. I see the report in the media, yes.

Q. And then it goes on to report how his doctor has been indicted for illegally prescribing prescription opioids to this professional wrestler; do you see that?

A. I see that. I'm not familiar with that physician.

Q. Sure. And then it goes on to describe the illegal drugs that this doctor was accused of giving to his patients in Georgia, which included methadone, Percocet, Oxycontin, Demerol and Xanax. Do you see that?

A. I see where it says that, yes.

Q. And I don't -- I probably belabored this point maybe more than I needed to, but you were getting these reports on a weekly basis, sending them out to people within Cephalon, and they would regularly -- maybe not always -- but regularly include stories about abuse, addiction, and diversion; right?

A. That's correct.

Q. And a lot of these articles focus on OxyContin and hydrocodone; right?

A. That's correct.

Q. And you've kind of gone out of your way to point out that Cephalon, at the time that you worked there, were not -- was not in the business of manufacturing hydrocodone or oxycodone; right?

A. That is correct.

Q. Would it surprise you that after you left, and in 2016 and 2017, Teva -- Teva's products containing hydrocodone, oxycodone and oxymorphone filled close to two million individual prescriptions in the state of Tennessee?

MR. JAMES: Objection.

THE WITNESS: I would not be aware of those statistics.

BY MR. GASTEL:

Q. But you've gone out of your way today to point out in these articles and in your testimony with Mr. Cartmell that Cephalon and Teva were not producing these types of opioids; right?

A. I went out of my way --

MR. JAMES: Objection.

THE WITNESS: -- to suggest that Cephalon did not do that. Teva has a generic business.

MR. GASTEL: Sure.

THE WITNESS: And that was not part of the

Cephalon business. And I was not aware and had no information regarding the Teva generic business in that regard. So I cannot speak to those statistics.
BY MR. GASTEL:
Q. And I understand that. But would it cause you concern, since you've kind of gone out of your way today to point out that when you were at Cephalon, they weren't making those products. You seemed to make that an important distinction in these articles that we just went through, to learn that Cephalon and Teva, after you left there, became major players in the hydrocodone and oxycodone and oxymorphone market?
MR. JAMES: Objection.
THE WITNESS: I don't have enough information to respond to that.
BY MR. GASTEL:
Q. And that's not my question. My question is not -- I'm not asking you to verify that. I'm asking you if it causes you concern?
MR. JAMES: Objection.
THE WITNESS: I don't have a context for the numbers of those prescriptions.
BY MR. GASTEL:
Q. And, again, I'm not asking you to --

about the context. But you have gone out of your way to say, hey, that wasn't us today, when we've been reviewing these articles; right?
A. That it wasn't Cephalon, yes.
Q. Yeah. And now, if it did become Cephalon, and it did become Teva, does that cause you concern?
MR. JAMES: Objection.
THE WITNESS: I have -- I do not know whether -- have any information about whether Teva's products -- how they were used or not, used appropriately or inappropriately. I was not at the company at that time.
BY MR. GASTEL:
Q. Were you at all involved in Teva's attempts to launch an abuse deterrent form of hydrocodone?
A. They were -- there was some research in that regard, I believe, right before I left. But I don't recall the timing.
Q. Sure. And I'm going to hand you a document that we will mark as Exhibit 36.
(Exhibit No. 36 was marked.)
MR. GASTEL: And for whatever reason, I didn't get my cover page that came with this. But

just for the record, this is produced to us in native format, TEVA, underscore, MDL, underscore, A, underscore, 04004373.
Q. And I want to direct your attention to this particular PowerPoint presentation carries just standard page numbers.
A. Okay.
Q. Can I direct your attention to pages 21 and 22. Let's begin with 21.
A. Yes.
Q. This is the AD hydrocodone functional team members slide. Do you see that?
A. Yes.
Q. And is it your understanding that the term AD hydrocodone is abuse deterrent hydrocodone?
A. Yes.
Q. And then if you look under the PR and government affairs team, you're listed there as health advocacy. Do you see that?
A. That's -- I was a consultant to Teva at that time.
Q. And I understand that. And then if you flip to the next page, there's the next AD hydrocodone team member overlap. Do you see that at the top?

A. Yes.
Q. And then if you look in the dark blue overlap, about midway down in the second column, you're also listed there, Stacey Beckhardt.
A. I was a consultant to Teva at that time.
Q. And so do you recall being present when this presentation was given?
A. I don't recall. But I don't -- it's possible that I was there.
Q. Let's flip to, again, page 12 real quick. Well, let me flip back to the front. This is dated April 16, 2013. It's on the front page, ma'am.
A. Yes.
Q. And that is years after we have been looking at these articles about widespread of abuse and misuse of opioids, especially in the south; correct?
A. It is several years later, yes.
Q. And then if you look on page 12, it says:
(Reading) Pain is an attractive and growing TA for global investment (end of reading).
Do you see that?

A. Yes.
Q. Do you know what TA stands for there?
A. No, I do not.
Q. And then underneath that it says:
(Reading) Global Pain Market Expected growth, $51 billion in 2011 and $68 billion by 2020 (end of reading).
Do you see that?
A. Yes.
Q. So if I'm reading that correctly, this appears that Teva -- it's Teva at that point; right?
A. Yes.
Q. That Teva expects the global pain market to grow $17 billion over the nine-year period reflected there; right?
A. That's what it states.
Q. And so -- and that's despite Teva at this point -- well, this is years after you've sent those articles around about widespread abuse and misuse of prescription opioids; right?
A. They were -- they were -- many of those people were not the same people, as those were in Teva.
Q. But certainly there were some people

who were still there --
A. There was some --
Q. -- right?
A. -- overlap. Yes, there was some overlap.
Q. You, including some of the people who were reviewing those news articles and then also part of this attempt to launch the abuse deterrent form of hydrocodone; right?
A. Yes, which was a -- which was intended to mitigate some of the challenges with abuse.
Q. Sure. And the -- and the hope was that this new abuse deterrent version of hydrocodone could displace the current versions of hydrocodone on the market and, therefore, hopefully lead to less abuse and diversion of hydrocodone; right?
MR. JAMES: Objection.
THE WITNESS: I -- you know, as a consultant, I can't say exactly what Teva's marketing strategy was in that regard.
BY MR. GASTEL:
Q. But it's kind of -- it's common sense that -- and I think that your testimony was that the abuse deterrent form was hopefully going to combat

some of the abuse and misuse that we have looked at in some of these articles; right?
A. That's correct.
Q. And that would only happen -- and, again, I think that this is common sense -- if the new abuse deterrent form of hydrocodone displaced the forms of hydrocodone that were leading to abuse and misuse in those articles that we reviewed; right?
MR. JAMES: Objection.
THE WITNESS: That also assumes that the abuse deterrent products had that efficacy.
BY MR. GASTEL:
Q. And -- but that was the hope in trying to develop this abuse deterrent form of hydrocodone; right?
MR. JAMES: Objection.
THE WITNESS: That was the hope.
BY MR. GASTEL:
Q. And do you know if Teva's -- well, is it your understanding that this abuse form of hydrocodone eventually was given the name of Vantrela?
A. I'm not aware of that.
Q. Are you aware of whether or not this ever -- this project ever got off the ground for

Teva?
A. I am not aware.
Q. Are you aware that they eventually got FDA approval for Vantrela, but nevertheless decided not to market it?
A. I'm not aware of that.
MR. GASTEL: Ms. Beckhardt, I think this will be music to your ears, but subject to my previous objection, that's all the questions I have for you.
MR. JAMES: I think we're done.
THE VIDEOGRAPHER: This concludes the video deposition of Stacey Beckhardt. We are going off the record at 7:48 p.m.
(The deposition was concluded at 7:48 p.m.)
--o0o--

Please be advised I have read the foregoing deposition, and I state there are:

(Check one) _____NO CORRECTIONS

_____CORRECTIONS PER ATTACHED

_____

STACEY BECKHARDT

DEPONENT'S CHANGES OR CORRECTIONS

Note: If you are adding to your testimony, print the exact words you want to add If you are deleting from your testimony, print the exact words you want to delete Specify with "Add" or "Delete" and sign this form

DEPOSITION OF: STACEY BECKHARDT

CASE: IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

DATE OF DEPOSITION: FEBRUARY 1, 2019

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DEPONENT'S SIGNATURE _____

DATE_____

CERTIFICATE OF REPORTER

I, SANDRA BUNCH VANDER POL, a Certified Shorthand Reporter, hereby certify that the witness in the foregoing deposition was by me duly sworn to tell the truth, the whole truth and nothing but the truth in the within-entitled cause;

That said deposition was taken down in shorthand by me, a disinterested person, at the time and place therein stated, and that the testimony of the said witness was thereafter reduced to typewriting, by computer, under my direction and supervision;

That before completion of the deposition, review of the transcript was requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

I further certify that I am not of counsel or attorney for either or any of the parties to the said deposition, nor in any way interested in the event of this cause, and that I am not related to any of the parties thereto.

DATED: FEBRUARY 4, 2019

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SANDRA BUNCH VANDER POL, CSR 3032